



US009474561B2

(12) **United States Patent**  
**Shemwell et al.**

(10) **Patent No.:** **US 9,474,561 B2**  
(45) **Date of Patent:** **Oct. 25, 2016**

(54) **TWO-WIRE TECHNIQUE FOR INSTALLING  
HAMMERTOE IMPLANT**

(56) **References Cited**

U.S. PATENT DOCUMENTS

(71) Applicant: **Wright Medical Technology, Inc.**,  
Arlington, TN (US)

(72) Inventors: **Jessica Lauren Shemwell**,  
Drummonds, TN (US); **Daniel Francis  
McCormick**, Memphis, TN (US)

321,389 A	6/1885	Schirmer
346,148 A	7/1886	Durham
348,589 A	9/1886	Sloan
373,074 A	11/1887	Jones
430,236 A	6/1890	Rogers
561,968 A	6/1896	Coulon

(Continued)

(73) Assignee: **Wright Medical Technology, Inc.**,  
Memphis, TN (US)

FOREIGN PATENT DOCUMENTS

(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 257 days.

CN	201085677	7/2008
EP	0127994	12/1984

(Continued)

OTHER PUBLICATIONS

(21) Appl. No.: **14/083,631**

U.S. Appl. No. 13/086,136—Non-Final Office Action dated Feb. 4,  
2013, 6 pages.

(22) Filed: **Nov. 19, 2013**

(Continued)

(65) **Prior Publication Data**

US 2015/0142066 A1 May 21, 2015

*Primary Examiner* — Christian Sevilla

*Assistant Examiner* — Eric S Gibson

(74) *Attorney, Agent, or Firm* — Duane Morris LLP

(51) **Int. Cl.**

**A61B 17/72** (2006.01)

**A61B 17/88** (2006.01)

**A61B 17/56** (2006.01)

(52) **U.S. Cl.**

CPC ..... **A61B 17/8888** (2013.01); **A61B 17/7291**  
(2013.01); **A61B 17/8883** (2013.01); **A61B**  
**2017/564** (2013.01)

(58) **Field of Classification Search**

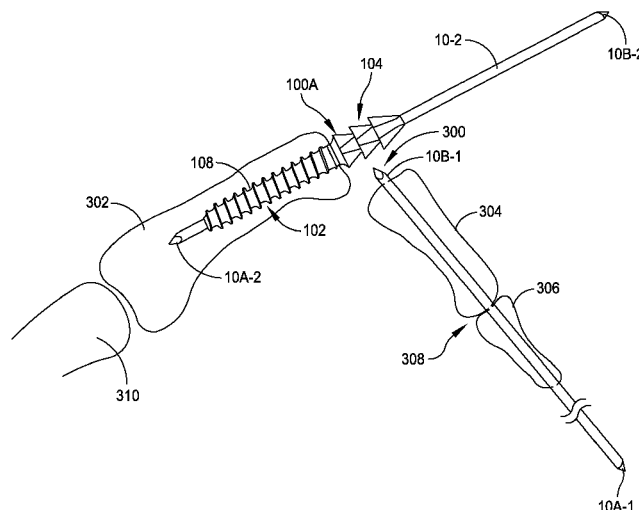
CPC ..... A61B 17/72; A61B 17/208; A61B  
17/7216; A61B 17/7225; A61B 17/7233;  
A61B 17/7283; A61B 17/7291; A61B 17/88;  
A61B 17/8875; A61B 17/8877; A61B  
17/8883; A61B 17/8886; A61B 17/8891;  
A61B 17/8897; A61B 2017/564

See application file for complete search history.

(57) **ABSTRACT**

A method includes inserting a first surgical device into an exposed first end of a first bone until a trailing end of the first surgical device is disposed adjacent to the first end of the first bone. A second surgical device is inserted into an exposed first end of a second bone while the first surgical device remains disposed within the first bone. A first portion of an implant is advanced into the second bone while being engaged with a passageway defined by the implant such that the implant is guided by the second surgical device. The second surgical device is removed from the second bone and from its engagement with the implant. The first bone is repositioned such that the first surgical device is aligned with the passageway defined by the implant, and the first bone is forced into engagement with a second portion of the implant.

**16 Claims, 39 Drawing Sheets**



(56)

## References Cited

## U.S. PATENT DOCUMENTS

736,121	A	8/1903	Lipscomb	5,029,753	A	7/1991	Hipon et al.
821,025	A	5/1906	Davies	5,037,440	A	8/1991	Koenig
882,937	A	3/1908	Pegley	5,046,513	A	9/1991	Gattorna et al.
1,966,835	A	7/1934	Stites	5,047,059	A	9/1991	Saffar
2,140,749	A	12/1938	Kaplan	5,053,038	A	10/1991	Sheehan
2,361,107	A	10/1944	Johnson	5,059,193	A	10/1991	Kuslich
2,451,747	A	10/1948	Kindt	5,062,851	A	11/1991	Branemark
2,490,364	A	12/1949	Livingston	5,089,009	A	2/1992	Green
2,600,517	A	6/1952	Rushing	5,092,896	A	3/1992	Meuli et al.
2,697,370	A	12/1954	Brooks	5,108,395	A	4/1992	Laurain
2,832,245	A	4/1958	Burrows	5,133,761	A	7/1992	Krouskop
2,895,368	A	7/1959	Place	5,147,363	A	9/1992	Harle
3,462,765	A	8/1969	Swanson	5,171,252	A	12/1992	Friedland
3,466,669	A *	9/1969	Flatt	5,179,915	A	1/1993	Cohen et al.
			A61F 2/4241	5,190,546	A	3/1993	Jervis
			623/21.17	5,199,839	A	4/1993	DeHaitre
3,593,342	A	7/1971	Niebauer et al.	5,207,712	A	5/1993	Cohen
3,681,786	A	8/1972	Lynch	5,209,756	A	5/1993	Seedhom et al.
3,739,403	A	6/1973	Nicolle	5,213,347	A	5/1993	Rulon et al.
3,759,257	A	9/1973	Fischer et al.	5,222,975	A	6/1993	Crainich
3,760,802	A	9/1973	Fischer et al.	5,246,443	A	9/1993	Mai
3,779,239	A	12/1973	Fischer et al.	5,281,225	A	1/1994	Vicenzi
3,824,631	A	7/1974	Burstein et al.	5,304,204	A	4/1994	Bregen
D243,716	S	3/1977	Treace et al.	5,324,307	A	6/1994	Jarrett et al.
4,047,524	A	9/1977	Hall	5,326,364	A	7/1994	Clift, Jr. et al.
4,096,896	A	6/1978	Engel	5,326,366	A	7/1994	Pascarella et al.
4,156,296	A	5/1979	Johnson et al.	5,330,476	A	7/1994	Hiot et al.
4,170,990	A	10/1979	Baumgart et al.	5,342,396	A	8/1994	Cook
4,175,555	A	11/1979	Herbert	5,352,229	A	10/1994	Goble et al.
4,198,713	A	4/1980	Swanson	5,354,301	A	10/1994	Castellano
4,204,284	A	5/1980	Koeneman	5,358,405	A	10/1994	Imai
4,213,208	A	7/1980	Marne	5,360,450	A	11/1994	Giannini
4,237,875	A	12/1980	Termanini	5,366,479	A	11/1994	McGarry et al.
4,262,665	A	4/1981	Roalstad et al.	5,380,334	A	1/1995	Torrie et al.
4,263,903	A	4/1981	Griggs	5,395,372	A	3/1995	Holt et al.
4,275,717	A	6/1981	Bolesky	5,405,400	A	4/1995	Linscheid et al.
4,276,660	A	7/1981	Laure	5,405,401	A	4/1995	Lippincott, III et al.
4,278,091	A	7/1981	Borzone	5,417,692	A	5/1995	Goble et al.
4,304,011	A	12/1981	Whelan, III	5,425,776	A	6/1995	Cohen
4,321,002	A	3/1982	Froehlich	5,425,777	A	6/1995	Sarkisian et al.
4,364,382	A	12/1982	Mennen	5,437,674	A	8/1995	Worcel et al.
4,367,562	A	1/1983	Gauthier	5,449,359	A	9/1995	Groiso
4,404,874	A	9/1983	Lieser	5,454,814	A	10/1995	Comte
4,434,796	A	3/1984	Karapetian et al.	5,458,648	A	10/1995	Berman et al.
4,454,875	A	6/1984	Pratt et al.	5,470,230	A	11/1995	Daftary et al.
4,485,816	A	12/1984	Krumme	5,474,557	A	12/1995	Mai
D277,509	S	2/1985	Lawrence et al.	5,480,447	A *	1/1996	Skiba
D277,784	S	2/1985	Sgariato et al.				A61F 2/4225
4,516,569	A	5/1985	Evans et al.	5,484,443	A	1/1996	Pascarella et al.
4,570,623	A	2/1986	Ellison et al.	5,498,265	A	3/1996	Asnis et al.
4,590,928	A	5/1986	Hunt et al.	5,507,822	A	4/1996	Bouchon et al.
D284,099	S	6/1986	Laporta et al.	5,516,248	A	5/1996	DeHaitre
4,634,382	A	1/1987	Kusano et al.	5,522,903	A	6/1996	Sokolow et al.
4,642,122	A	2/1987	Steffe	5,529,075	A	6/1996	Clark
4,655,661	A	4/1987	Brandt	5,536,127	A	7/1996	Pennig
D291,731	S	9/1987	Alkins	5,549,681	A	8/1996	Segmüller et al.
4,723,540	A	2/1988	Gilmer, Jr.	5,551,871	A	9/1996	Besselink et al.
4,723,541	A	2/1988	Reese	5,554,157	A	9/1996	Errico et al.
4,731,087	A	3/1988	Sculco et al.	5,578,034	A	11/1996	Estes
4,756,711	A	7/1988	Mai et al.	5,591,165	A	1/1997	Jackson
4,759,768	A	7/1988	Hermann et al.	5,595,563	A	1/1997	Moison
4,790,304	A	12/1988	Rosenberg	5,601,558	A	2/1997	Torrie et al.
4,865,606	A	9/1989	Rehder	D378,409	S	3/1997	Michelson
4,908,031	A	3/1990	Frisch	5,634,925	A	6/1997	Urbanski
4,915,092	A	4/1990	Firica et al.	5,643,264	A	7/1997	Sherman et al.
4,932,974	A	6/1990	Pappas et al.	5,645,599	A	7/1997	Samani
4,940,467	A	7/1990	Tronzo	5,660,188	A	8/1997	Groiso
4,955,916	A	9/1990	Carignan et al.	5,669,913	A	9/1997	Zobel
4,963,144	A	10/1990	Huene	5,674,297	A	10/1997	Lane et al.
4,969,909	A *	11/1990	Barouk	5,683,466	A *	11/1997	Vitale
			A61B 17/72				A61F 2/30756
			606/62				623/21.15
5,002,563	A	3/1991	Pyka et al.	5,690,629	A	11/1997	Asher et al.
5,007,932	A	4/1991	Bekki et al.	5,702,472	A	12/1997	Huebner
5,011,497	A *	4/1991	Persson	5,707,395	A	1/1998	Li
			A61F 2/4241	5,713,903	A	2/1998	Sander et al.
			623/21.15	5,713,904	A	2/1998	Errico et al.
5,019,079	A	5/1991	Ross	5,720,753	A	2/1998	Sander et al.
				5,725,585	A	3/1998	Zobel
				5,728,127	A	3/1998	Asher et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

5,733,307 A	3/1998	Dinsdale	6,811,568 B2	11/2004	Minamikawa
5,741,256 A	4/1998	Bresina	6,869,449 B2	3/2005	Ball et al.
5,749,916 A	5/1998	Richelsoph	6,875,235 B2	4/2005	Ferree
5,769,852 A	6/1998	Brångemark	7,037,309 B2 *	5/2006	Weil ..... A61B 17/863
5,776,202 A	7/1998	Copf et al.			606/304
5,779,707 A	7/1998	Berthelet et al.	7,037,324 B2	5/2006	Martinek
5,782,927 A	7/1998	Klawitter et al.	7,037,342 B2	5/2006	Nilsson et al.
5,785,713 A	7/1998	Jobe	7,041,106 B1 *	5/2006	Carver ..... A61B 17/291
5,840,078 A	11/1998	Yerys			606/309
5,853,414 A	12/1998	Groiso	7,044,953 B2	5/2006	Capanni
5,876,434 A	3/1999	Flomenblit et al.	7,112,214 B2	9/2006	Peterson et al.
5,882,444 A	3/1999	Flomenblit et al.	7,182,787 B2	2/2007	Hassler et al.
5,893,850 A	4/1999	Cachia	7,192,445 B2	3/2007	Ellingsen et al.
5,919,193 A	7/1999	Slavitt	7,207,994 B2	4/2007	Vlahos et al.
5,928,236 A	7/1999	Augagneur et al.	7,240,677 B2	7/2007	Fox
5,941,890 A	8/1999	Voegelé et al.	7,261,716 B2	8/2007	Strobel
5,951,288 A	9/1999	Sawa	7,291,175 B1	11/2007	Gordon
5,958,159 A	9/1999	Prandi	7,569,061 B2	8/2009	Colleran
5,980,524 A	11/1999	Justin et al.	7,585,316 B2	9/2009	Trieu
5,984,970 A	11/1999	Bramlet	7,588,603 B2	9/2009	Leonard
5,984,971 A	11/1999	Faccioli et al.	7,695,471 B2	4/2010	Cheung et al.
6,011,497 A	1/2000	Tsang et al.	7,708,759 B2	5/2010	Lubbers et al.
6,017,366 A	1/2000	Berman	7,727,235 B2	6/2010	Contiliano et al.
6,030,162 A	2/2000	Huebner	7,780,701 B1	8/2010	Meridew et al.
6,045,573 A	4/2000	Wenstrom et al.	7,780,737 B2	8/2010	Bonnard et al.
6,048,151 A	4/2000	Kwee	7,785,357 B2	8/2010	Guan et al.
6,048,343 A	4/2000	Mathis et al.	7,837,738 B2	11/2010	Reigstad et al.
6,083,242 A	7/2000	Cook	7,842,091 B2	11/2010	Johnstone et al.
6,099,571 A	8/2000	Knapp	7,887,589 B2	2/2011	Glenn et al.
6,102,642 A	8/2000	Kawashita et al.	7,909,880 B1	3/2011	Grant
6,146,387 A	11/2000	Trott et al.	7,918,879 B2	4/2011	Yeung et al.
6,187,009 B1	2/2001	Herzog et al.	7,959,681 B2	6/2011	Lavi
6,193,757 B1	2/2001	Foley et al.	7,963,995 B2	6/2011	Richelsoph
6,197,037 B1	3/2001	Hair	7,976,565 B1	7/2011	Meridew
6,200,321 B1	3/2001	Orbay et al.	7,985,246 B2	7/2011	Trieu
6,200,330 B1	3/2001	Benderev et al.	8,002,811 B2	8/2011	Corradi et al.
6,200,345 B1	3/2001	Morgan	8,057,524 B2	11/2011	Meridew
6,224,600 B1	5/2001	Protogirou	8,100,983 B2	1/2012	Schulte
6,248,109 B1	6/2001	Stofella	8,118,839 B2	2/2012	Taylor
6,299,613 B1	10/2001	Ogilvie et al.	8,118,849 B2	2/2012	Wahl et al.
6,305,053 B1	10/2001	Galbreath	8,197,509 B2	6/2012	Contiliano et al.
6,306,140 B1	10/2001	Siddiqui	8,262,712 B2	9/2012	Coilard-Lavirotte et al.
6,319,284 B1	11/2001	Rushdy et al.	8,267,939 B2	9/2012	Cipoletti et al.
6,332,885 B1	12/2001	Martella	8,337,537 B2	12/2012	Pelo et al.
6,336,928 B1	1/2002	Guerin et al.	8,394,097 B2	3/2013	Peyrot et al.
6,352,560 B1	3/2002	Poeschmann et al.	8,394,132 B2	3/2013	Lewis et al.
6,383,223 B1	5/2002	Baehler et al.	8,414,583 B2	4/2013	Prandi et al.
6,386,877 B1	5/2002	Sutter	8,465,525 B2	6/2013	Hawkins et al.
6,406,234 B2	6/2002	Frigg	8,475,456 B2	7/2013	Augoyard et al.
6,413,260 B1	7/2002	Berrevoets et al.	8,523,944 B2	9/2013	Jimenez et al.
6,419,706 B1	7/2002	Graf	8,591,545 B2	11/2013	Lunn et al.
6,423,097 B2	7/2002	Rauscher	8,608,785 B2	12/2013	Reed et al.
6,428,634 B1	8/2002	Besslink et al.	8,616,091 B2	12/2013	Anderson
6,436,099 B1	8/2002	Drewry et al.	8,636,457 B2	1/2014	Connors
6,451,057 B1	9/2002	Chen et al.	8,641,769 B2	2/2014	Malandain
6,454,808 B1	9/2002	Masada	8,647,390 B2	2/2014	Bellemere et al.
6,458,134 B1	10/2002	Songer et al.	8,764,842 B2	7/2014	Graham
6,475,242 B1	11/2002	Bramlet	8,840,677 B2	9/2014	Kale et al.
6,508,841 B2	1/2003	Martin et al.	8,888,779 B2	11/2014	Senn
6,517,543 B1	2/2003	Berrevoets et al.	D720,072 S	12/2014	Cheney et al.
6,533,788 B1	3/2003	Orbay	8,906,060 B2	12/2014	Hart
6,551,321 B1	4/2003	Burkinshaw	8,986,386 B2	3/2015	Oglaza et al.
6,551,343 B1	4/2003	Törmälä et al.	8,998,999 B2	4/2015	Lewis et al.
6,575,973 B1	6/2003	Shekalim	9,044,287 B2	6/2015	Reed et al.
6,575,976 B2	6/2003	Grafton	9,056,014 B2	6/2015	McCormick et al.
6,582,453 B1	6/2003	Tran et al.	9,125,704 B2	9/2015	Reed et al.
6,648,890 B2	11/2003	Culbert et al.	9,138,274 B1 *	9/2015	Biesinger ..... A61B 17/225
6,679,668 B2	1/2004	Martin et al.	9,149,268 B2	10/2015	Graul et al.
6,682,565 B1	1/2004	Krishnan	2001/0025199 A1	9/2001	Rauscher
6,685,706 B2	2/2004	Padget et al.	2001/0028836 A1	10/2001	Kohori
6,699,247 B2	3/2004	Zucherman et al.	2001/0049529 A1	12/2001	Cachia et al.
6,699,292 B2	3/2004	Ogilvie et al.	2002/0019636 A1	2/2002	Ogilvie et al.
6,706,045 B2	3/2004	Lin et al.	2002/0022887 A1	2/2002	Huene
6,767,350 B1	7/2004	Lob	2002/0026194 A1	2/2002	Morrison et al.
6,773,437 B2	8/2004	Ogilvie et al.	2002/0055785 A1	5/2002	Harris
			2002/0065561 A1	5/2002	Ogilvie et al.
			2002/0068939 A1	6/2002	Levy et al.
			2002/0072803 A1	6/2002	Saunders et al.
			2002/0082705 A1	6/2002	Bouman et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2002/0111690	A1	8/2002	Hyde	2008/0221697	A1	9/2008	Graser	
2002/0128713	A1	9/2002	Ferree	2008/0221698	A1	9/2008	Berger	
2002/0165544	A1	11/2002	Perren et al.	2008/0255618	A1	10/2008	Fisher et al.	
2002/0183846	A1	12/2002	Kuslich et al.	2008/0269908	A1	10/2008	Warburton	
2003/0032961	A1	2/2003	Pelo et al.	2008/0294204	A1	11/2008	Chirico et al.	
2003/0040805	A1	2/2003	Minamikawa	2009/0005782	A1	1/2009	Chirico et al.	
2003/0069645	A1	4/2003	Ball et al.	2009/0012564	A1	1/2009	Chirico et al.	
2003/0130660	A1	7/2003	Levy et al.	2009/0036893	A1	2/2009	Kartalian et al.	
2003/0191422	A1	10/2003	Sossong	2009/0149891	A1	6/2009	Lee et al.	
2003/0233095	A1	12/2003	Urbanski et al.	2009/0163918	A1	6/2009	Levy et al.	
2004/0010315	A1	1/2004	Song	2009/0187219	A1	7/2009	Pachtman et al.	
2004/0093081	A1	5/2004	Nilsson et al.	2009/0204158	A1	8/2009	Sweeney	
2004/0097941	A1	5/2004	Weiner et al.	2009/0210016	A1	8/2009	Champagne et al.	
2004/0102853	A1	5/2004	Boumann et al.	2009/0216282	A1	8/2009	Blake et al.	
2004/0111117	A1	6/2004	Colleran et al.	2009/0254189	A1	10/2009	Scheker	
2004/0133204	A1	7/2004	Davies	2009/0254190	A1	10/2009	Gannoe et al.	
2004/0138756	A1	7/2004	Reeder	2009/0259316	A1	10/2009	Ginn et al.	
2004/0220574	A1	11/2004	Pelo et al.	2010/0010637	A1	1/2010	Pequignot	
2004/0220678	A1	11/2004	Chow et al.	2010/0016982	A1	1/2010	Solomons	
2004/0230193	A1	11/2004	Cheung et al.	2010/0023012	A1	1/2010	Voor	
2004/0230194	A1	11/2004	Urbanski et al.	2010/0030221	A1	2/2010	Christian et al.	
2004/0230313	A1	11/2004	Saunders	2010/0049244	A1	2/2010	Cohen et al.	
2004/0249461	A1	12/2004	Ferree	2010/0057214	A1	3/2010	Graham et al.	
2005/0113836	A1	5/2005	Lozier et al.	2010/0061825	A1*	3/2010	Liu	B25B 13/08 411/388
2005/0119757	A1	6/2005	Hassler et al.	2010/0069913	A1	3/2010	Chirico	
2005/0123672	A1	6/2005	Justin et al.	2010/0069970	A1	3/2010	Lewis et al.	
2005/0124443	A1	6/2005	Summers	2010/0121390	A1	5/2010	Kleinman	
2005/0149031	A1	7/2005	Ciccone et al.	2010/0125274	A1	5/2010	Greenhalgh et al.	
2005/0177158	A1	8/2005	Doubler et al.	2010/0131014	A1	5/2010	Peyrot et al.	
2005/0187636	A1	8/2005	Graham	2010/0131072	A1*	5/2010	Schulte	A61B 17/68 623/21.11
2005/0251265	A1	11/2005	Calandrucchio et al.	2010/0161068	A1	6/2010	Lindner et al.	
2005/0261768	A1	11/2005	Trieu	2010/0185295	A1	7/2010	Emmanuel	
2005/0283159	A1	12/2005	Amara	2010/0217325	A1	8/2010	Hochschuler et al.	
2006/0052725	A1	3/2006	Santilli	2010/0249942	A1	9/2010	Goswami et al.	
2006/0052878	A1	3/2006	Schmieding	2010/0256639	A1*	10/2010	Tyber	A61B 17/1717 606/62
2006/0074421	A1	4/2006	Bickley et al.	2010/0256770	A1	10/2010	Hakansson et al.	
2006/0074488	A1	4/2006	Abdou	2010/0262254	A1	10/2010	Lawrence et al.	
2006/0074492	A1	4/2006	Frey	2010/0274293	A1	10/2010	Terrill et al.	
2006/0084998	A1	4/2006	Levy et al.	2010/0286692	A1	11/2010	Greenhalgh et al.	
2006/0100715	A1	5/2006	De Villiers	2010/0292799	A1	11/2010	Hansell et al.	
2006/0129153	A1*	6/2006	Klaue	2010/0324556	A1*	12/2010	Tyber	A61B 17/1717 606/62
				2010/0331893	A1	12/2010	Geist et al.	
2006/0149258	A1	7/2006	Sousa	2011/0004255	A1*	1/2011	Weiner	A61B 17/1682 606/301
2006/0173462	A1	8/2006	Kay et al.	2011/0004317	A1	1/2011	Hacking et al.	
2006/0200151	A1	9/2006	Ducharme et al.	2011/0066190	A1	3/2011	Schaller et al.	
2006/0229617	A1	10/2006	Meller et al.	2011/0082507	A1*	4/2011	Klaue	A61B 17/68 606/329
2006/0247787	A1	11/2006	Rydell et al.	2011/0082508	A1*	4/2011	Reed	A61B 17/7225 606/329
2007/0038303	A1	2/2007	Myerson et al.	2011/0093017	A1	4/2011	Prasad et al.	
2007/0078518	A1	4/2007	Lavi	2011/0093075	A1	4/2011	Duplessis et al.	
2007/0106283	A1	5/2007	Garcia et al.	2011/0093085	A1	4/2011	Morton	
2007/0123873	A1	5/2007	Czartoski et al.	2011/0118739	A1*	5/2011	Tyber	A61B 17/1717 606/62
2007/0123993	A1	5/2007	Hassler et al.	2011/0144644	A1*	6/2011	Prandi	A61B 17/68 606/62
2007/0142920	A1	6/2007	Niemi	2011/0144766	A1	6/2011	Kale et al.	
2007/0177959	A1	8/2007	Chopp et al.	2011/0208252	A1	8/2011	Erhart	
2007/0185583	A1	8/2007	Branemark	2011/0257652	A1*	10/2011	Roman	A61B 17/7225 606/62
2007/0185584	A1	8/2007	Kaufmann et al.	2011/0301652	A1*	12/2011	Reed	A61B 17/7291 606/319
2007/0198018	A1	8/2007	Biedermann et al.	2011/0301653	A1*	12/2011	Reed	A61B 17/1604 606/319
2007/0213831	A1	9/2007	de Cubber	2011/0306975	A1	12/2011	Kaikkonen et al.	
2007/0239158	A1	10/2007	Trieu et al.	2011/0319946	A1	12/2011	Levy et al.	
2007/0293866	A1	12/2007	Stroeckel et al.	2012/0016428	A1	1/2012	White et al.	
2008/0039949	A1	2/2008	Meesenburg et al.	2012/0065692	A1	3/2012	Champagne et al.	
2008/0051912	A1	2/2008	Hollawell	2012/0065738	A1*	3/2012	Schulman	A61B 17/68 623/23.44
2008/0086139	A1*	4/2008	Bourke	2012/0089197	A1*	4/2012	Anderson	A61B 17/7233 606/310
				2012/0136448	A1	5/2012	Seifert et al.	
2008/0132894	A1	6/2008	Coilard-Lavirotte et al.	2012/0209337	A1	8/2012	Weinstein	
2008/0132958	A1	6/2008	Pech et al.					
2008/0154385	A1	6/2008	Trail et al.					
2008/0161919	A1	7/2008	Melkent					
2008/0177262	A1	7/2008	Augoyard et al.					
2008/0177291	A1	7/2008	Jensen et al.					
2008/0177334	A1	7/2008	Stinnette					
2008/0195215	A1	8/2008	Morton					
2008/0195219	A1	8/2008	Wiley et al.					
2008/0221574	A1*	9/2008	Cavallazzi					

(56)	<b>References Cited</b>			EP	1825826	A1	8/2007
	U.S. PATENT DOCUMENTS			EP	1870050	A2	12/2007
				EP	1708653		9/2009
				EP	1923012		6/2010
2012/0259419	A1	10/2012	Brown et al.	EP	1868536		11/2010
2012/0271362	A1	10/2012	Martineau et al.	EP	2275055		5/2012
2012/0323241	A1	12/2012	McClellan et al.	EP	2221025		12/2012
2013/0030475	A1	1/2013	Weiner et al.	EP	2221026		3/2013
2013/0053975	A1	2/2013	Reed et al.	EP	2564799	A1	3/2013
2013/0060295	A1	3/2013	Reed et al.	EP	2774556	A1	9/2014
2013/0066383	A1*	3/2013	Anderson ..... A61B 17/7233	FR	736058		11/1932
			606/329	FR	1036978		9/1953
2013/0066435	A1*	3/2013	Averous ..... A61F 2/42	FR	2603794		3/1988
			623/21.11	FR	2605878		5/1988
2013/0079776	A1*	3/2013	Zwirkoski ..... A61B 17/68	FR	2628312		9/1989
			606/62	FR	2645735		10/1990
2013/0090655	A1	4/2013	Tontz	FR	2651119		3/1991
2013/0096634	A1	4/2013	Suh	FR	2663838	A1	1/1993
2013/0123862	A1*	5/2013	Anderson ..... A61B 17/88	FR	2694696		2/1994
			606/321	FR	2725126		4/1996
2013/0131822	A1*	5/2013	Lewis ..... A61F 2/4606	FR	2743490		7/1997
			623/21.19	FR	2754702		4/1998
2013/0150965	A1*	6/2013	Taylor ..... A61F 2/30	FR	2783702		3/2000
			623/16.11	FR	2787313		6/2000
2013/0190761	A1	7/2013	Prandi et al.	FR	2794019		12/2000
2013/0211451	A1	8/2013	Wales et al.	FR	2801189	A1	5/2001
2013/0226191	A1*	8/2013	Thoren ..... A61B 17/8886	FR	2846545		5/2004
			606/104	FR	2728779	A1	7/2005
2013/0253597	A1	9/2013	Augoyard et al.	FR	2884406		10/2006
2013/0274814	A1	10/2013	Weiner et al.	FR	2927529	A1	8/2009
2013/0317559	A1*	11/2013	Leavitt ..... A61B 17/1697	FR	2935601	A1	3/2010
			606/86 R	GB	140983		4/1920
2013/0325138	A1	12/2013	Graham	GB	2119655		11/1983
2014/0018930	A1*	1/2014	Oster ..... A61F 2/4261	GB	2227540		1/1990
			623/21.12	GB	2336415		10/1999
2014/0025125	A1	1/2014	Sack et al.	GB	2430625		4/2007
2014/0052196	A1*	2/2014	McGinley ..... A61B 17/8605	JP	S53-128181	A	11/1978
			606/319	JP	60145133		7/1985
2014/0107713	A1	4/2014	Pech et al.	JP	H07-500520	A	1/1995
2014/0135768	A1	5/2014	Roman	JP	07303662		11/1995
2014/0142715	A1*	5/2014	McCormick ..... A61B 17/8883	JP	2004535249		11/2004
			623/21.19	JP	2007530194		11/2007
2014/0180428	A1	6/2014	McCormick	JP	2008-188411	A	8/2008
2014/0188179	A1	7/2014	McCormick	JP	2009-160399	A	7/2009
2014/0188237	A1	7/2014	McCormick et al.	JP	2010-046481	A	3/2010
2014/0188239	A1*	7/2014	Cummings ..... A61B 17/7291	JP	2011-502584	A	1/2011
			623/21.19	JP	2011-525229	A	9/2011
2014/0257289	A1	9/2014	Kecman et al.	SU	1152582		4/1985
2014/0276825	A1	9/2014	Brown et al.	WO	WO 92/17122		10/1992
2014/0277185	A1	9/2014	Boileau et al.	WO	WO 96/41596		12/1996
2014/0277186	A1	9/2014	Granberry et al.	WO	WO 98/17189		4/1998
2015/0012098	A1	1/2015	Eastlack et al.	WO	WO 98/47449		10/1998
2015/0018954	A1	1/2015	Loebl et al.	WO	WO 99/21515	A1	5/1999
2015/0073413	A1*	3/2015	Palmer ..... A61B 17/7266	WO	WO 01/80751	A1	11/2001
			606/63	WO	WO 02/34107		5/2002
2015/0088136	A1	3/2015	Kotuljac et al.	WO	WO 2005/063149		7/2005
2015/0088266	A1	3/2015	Sander et al.	WO	WO2005094706		10/2005
2015/0094778	A1	4/2015	McCormick et al.	WO	WO 2005/104961		11/2005
2015/0112342	A1*	4/2015	Penzimer ..... A61B 17/8875	WO	WO 2006/103598		10/2006
			606/63	WO	WO2006109004		10/2006
2015/0141994	A1	5/2015	Cheney et al.	WO	WO2007135322		11/2007
2015/0142066	A1*	5/2015	Shemwell ..... A61B 17/8888	WO	WO 2009/155577		12/2009
			606/301	WO	WO 2013/096746		6/2013
2015/0164563	A1	6/2015	Lewis et al.	WO	WO 2013/131974	A1	9/2013
2015/0223848	A1	8/2015	McCormick et al.	WO	WO 2014/165123		10/2014
2015/0223849	A1*	8/2015	McCormick ..... A61B 17/7291	WO			
			606/63				
2015/0342655	A1	12/2015	Reed et al.				

## FOREIGN PATENT DOCUMENTS

EP	0340159	11/1989
EP	0409364	1/1991
EP	0545830	6/1993
EP	0551846	7/1993
EP	0611557	8/1994
EP	0738502	10/1996
EP	880950	A1 12/1998
EP	1300122	4/2003

## OTHER PUBLICATIONS

U.S. Appl. No. 13/086,136—Final Office Action dated Sep. 18, 2013, 9 pages.

U.S. Appl. No. 13/086,136—Non-Final Office Action dated Dec. 30, 2013, 11 pages.

U.S. Appl. No. 13/086,136—Final Office Action dated May 29, 2014, 14 pages.

U.S. Appl. No. 13/086,136—Advisory Action dated Oct. 10, 2014, 4 pages.

(56)

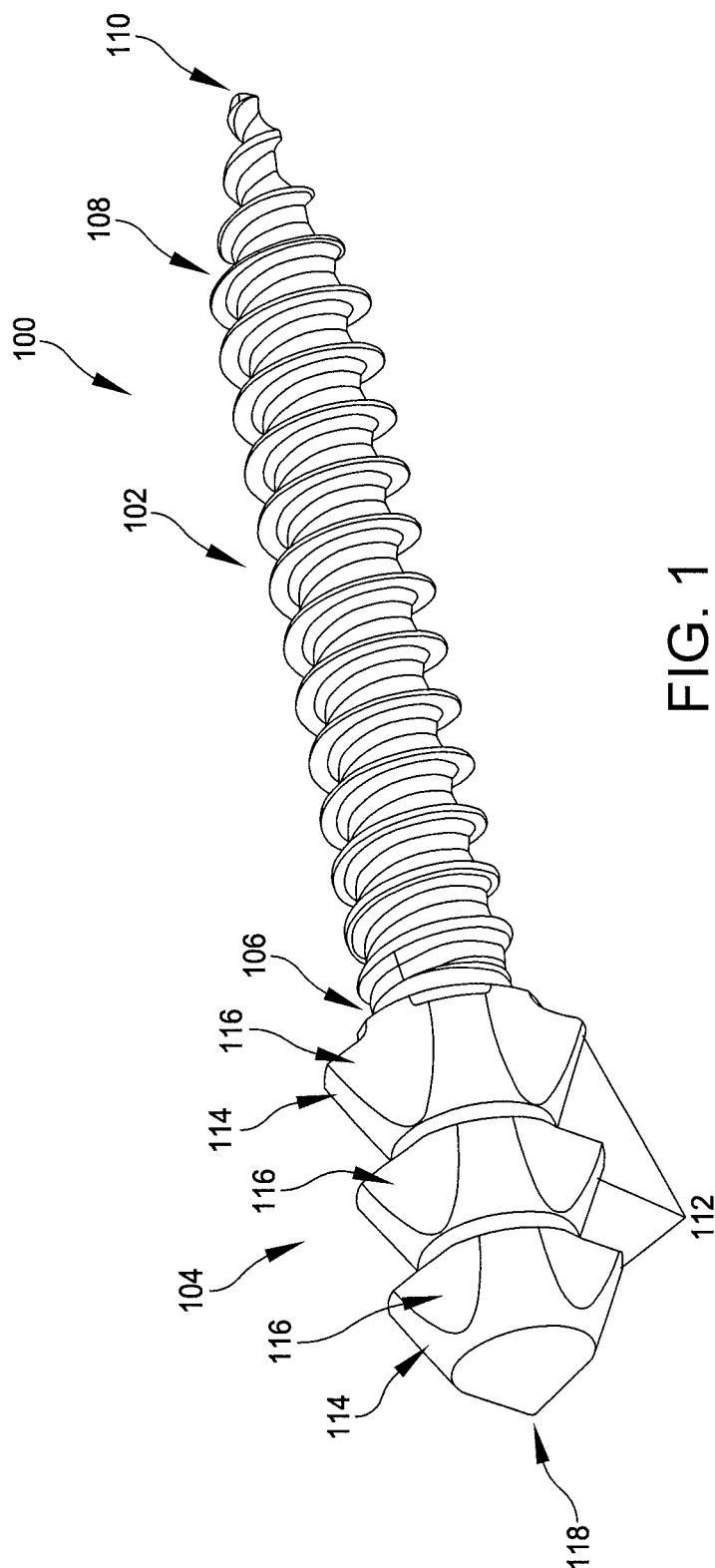
**References Cited**

**OTHER PUBLICATIONS**

U.S. Appl. No. 13/660,522—Non-Final Office Action dated Dec. 24, 2013, 9 pages.  
 U.S. Appl. No. 13/660,522—Final Office Action dated May 30, 2014, 13 pages.  
 U.S. Appl. No. 13/660,495—Non-final Office Action dated Dec. 26, 2013, 8 pages.  
 U.S. Appl. No. 13/660,495—Final Office Action dated May 29, 2014, 12 pages.  
 U.S. Appl. No. 13/660,495—Advisory Action dated Oct. 10, 2014, 4 pages.  
 Brochure MKT 016 A: iFuse HT Hammertoe Correction Implant, OrthoPro LLC, 2 pages, undated.  
 Brochure p/n 030-1788 Rev A: ExtremiFuse Hammertoe Fixation System, OsteoMED Small Bone Orthopedics, 6 pages, undated.  
 Brochure 900-01-008 Rev C: Hammer Toe Implant System Instructions for Use, Trilliant Surgical Ltd, 2 pages, undated.  
 Bensmann, et al., “Nickel-titanium Osteosynthesis Clips,” Reprint from Medical Focus, 1983.

Besselink, Sachdeva, “Applications of Shape Memory Effects,” Memory Metal Holland, Memory Medical Systems, Publication Date Unknown.  
 Dai, K.R., et al., “Treatment of Intra-Articular Fractures with Shape Memory Compression Staples,” Injury, (1993) 24, (IO), 651-655.  
 Haasters, Dr. J., et al., “The Use of Ni—Ti As An Implant Material in Orthopedics”, pp. 426-444.  
 Kuo, M.D., et al., “The Use of Nickel-Titanium Alloy in Orthopedic Surgery in China,” Orthopedics, Jan. 1989, vol. 12/No. 1.  
 Lu, M.D., Shibi, “Medical Applications of Ni—Ti Alloys in China,” pp. 445-451.  
 Ricart, “The Use of a Memory Shape Staple in Cervical Anterior Fusion,” Proceedings of the Second International Conference on Shape Memory and Superelastic Technologies, Asilomar Conference Center, Pacific Grove, CA, USA, Mar. 2-6, 1997.  
 Ricart, “The Use of a Memory-Shaple Staple in Cervical Anterior Fusion,” in Shape Memory Implants, Springer-Verlag Berlin Heidelberg, 2000.  
 Tang, Dai, Chen, “Application of a Ni—Ti Staple in the Metatarsal Osteotomy,” Bio-Medical Materials and Engineering 6, (1996), 307-312, IOS Press.

\* cited by examiner



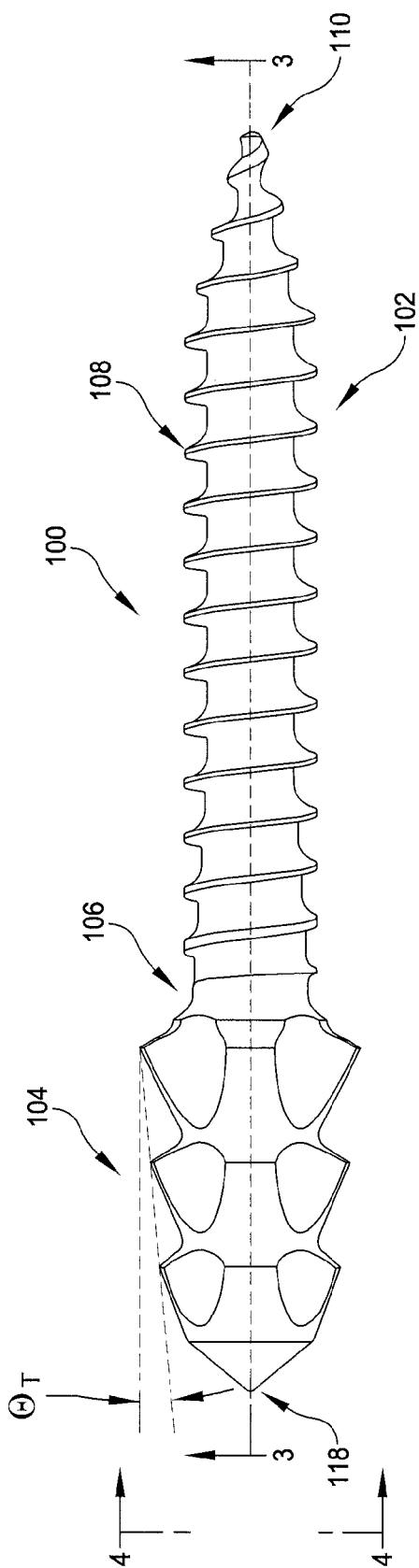


FIG. 2



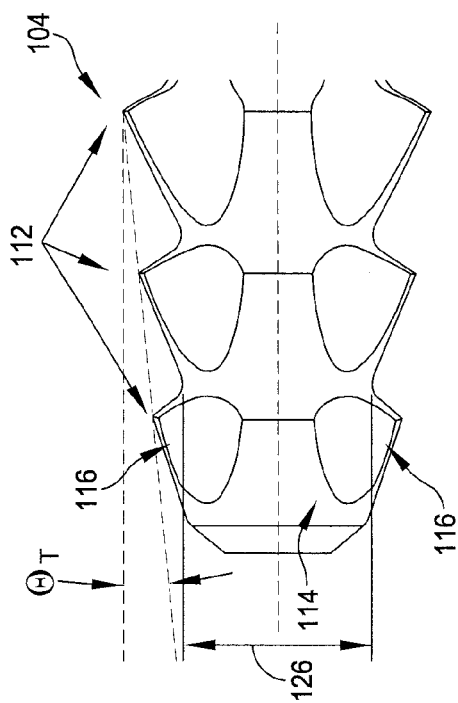


FIG. 3

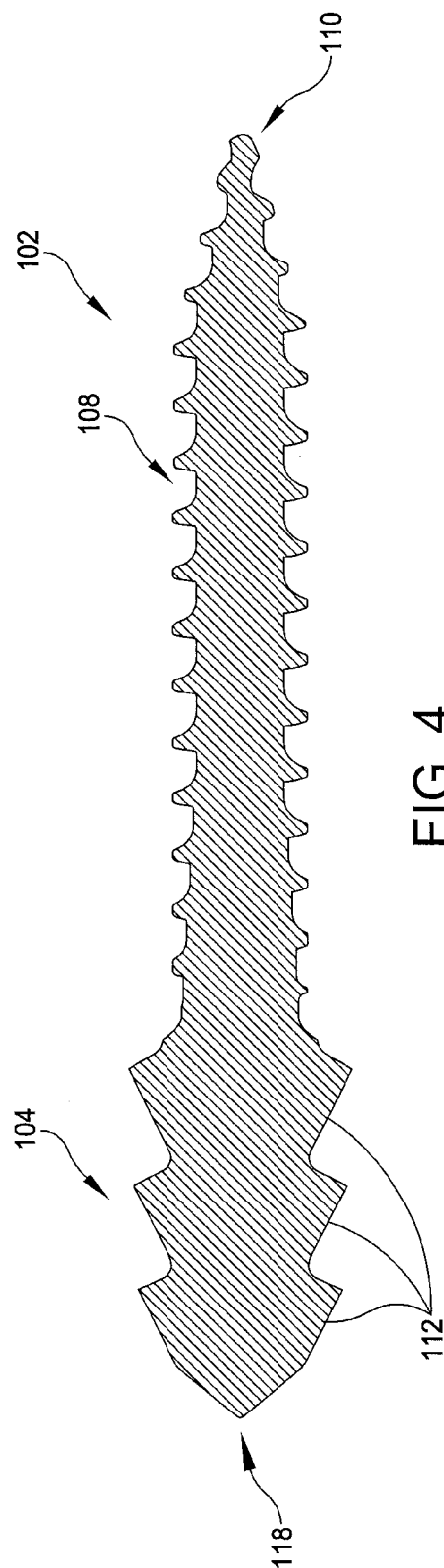


FIG. 4

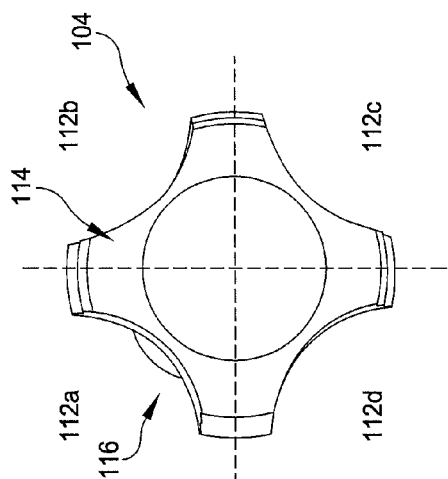


FIG. 5

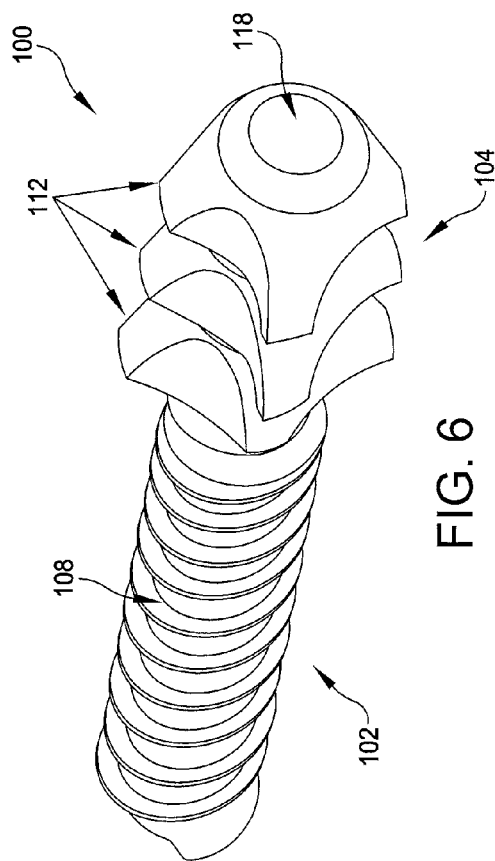


FIG. 6

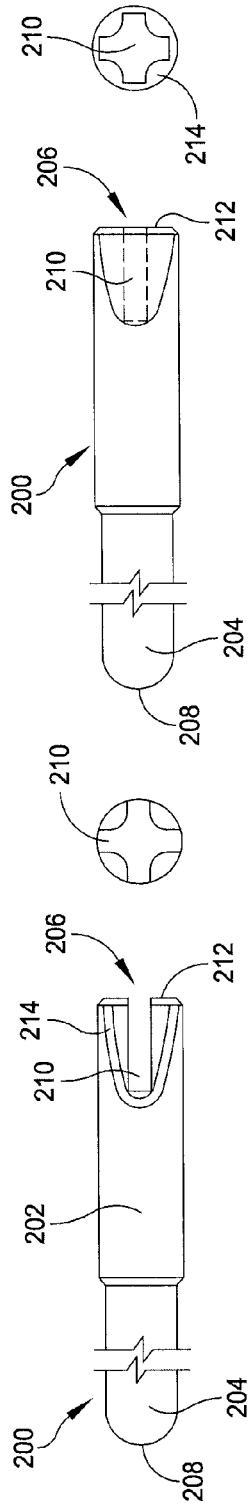


FIG. 10

FIG. 9

FIG. 8

FIG. 7

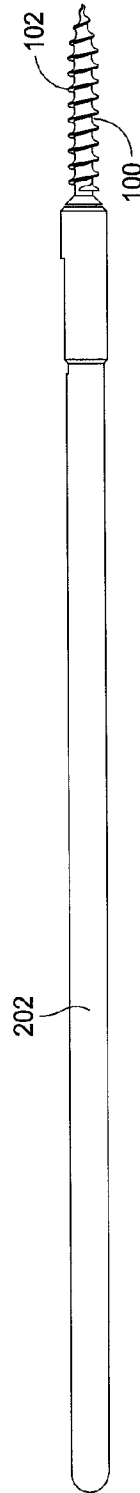


FIG. 11A



FIG. 11B

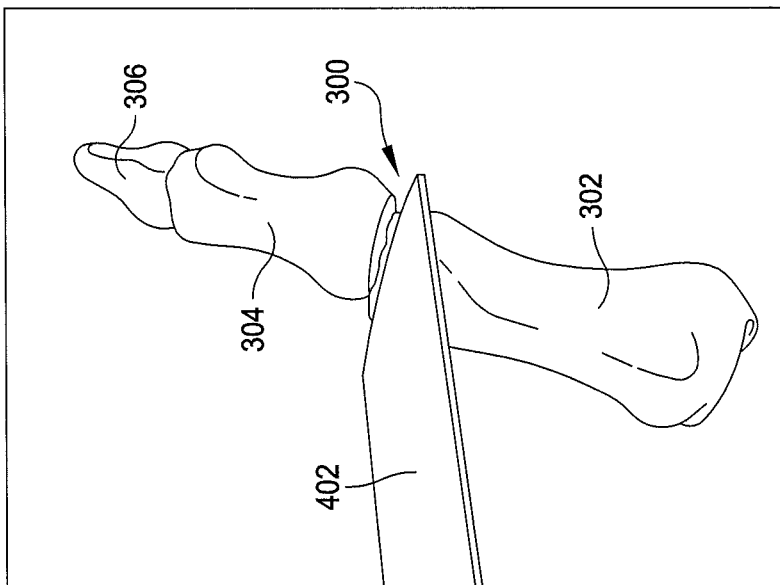


FIG. 12B

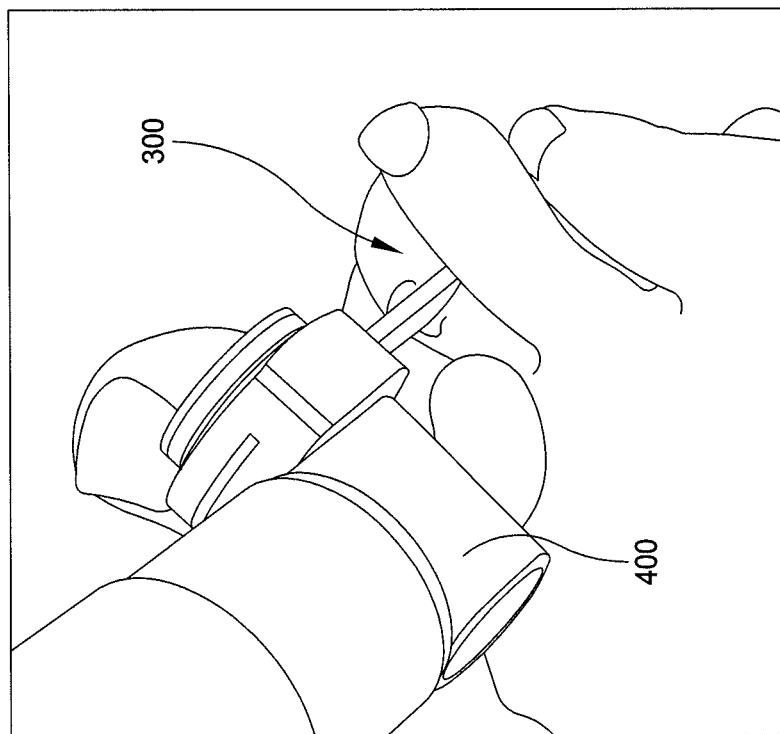


FIG. 12A

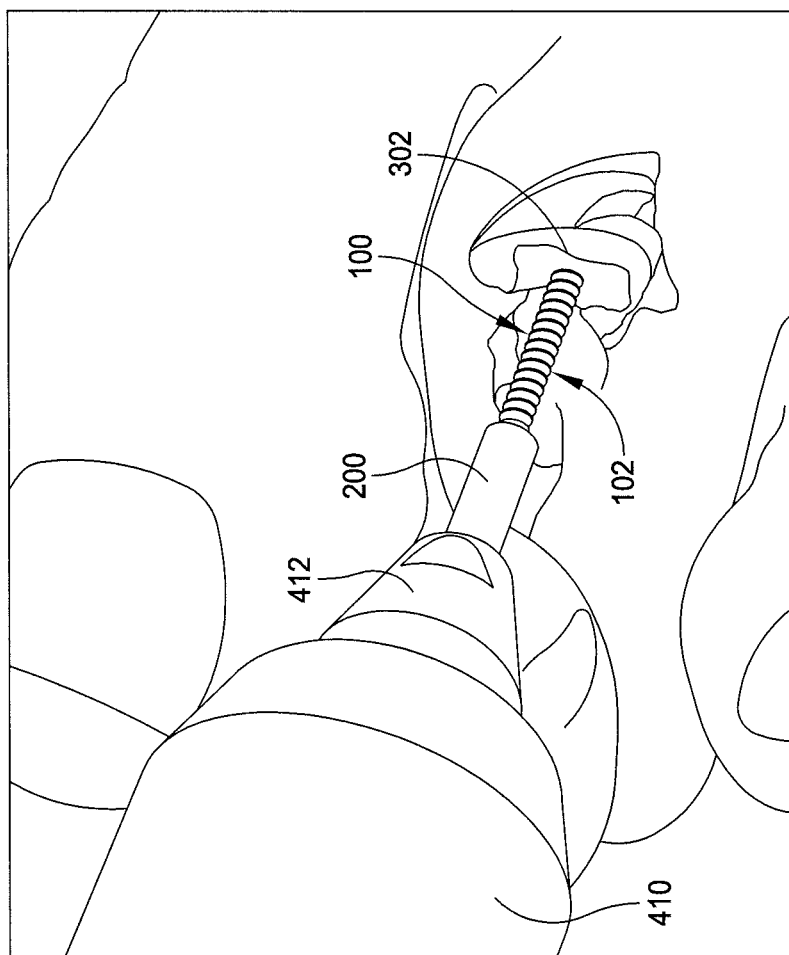


FIG. 13

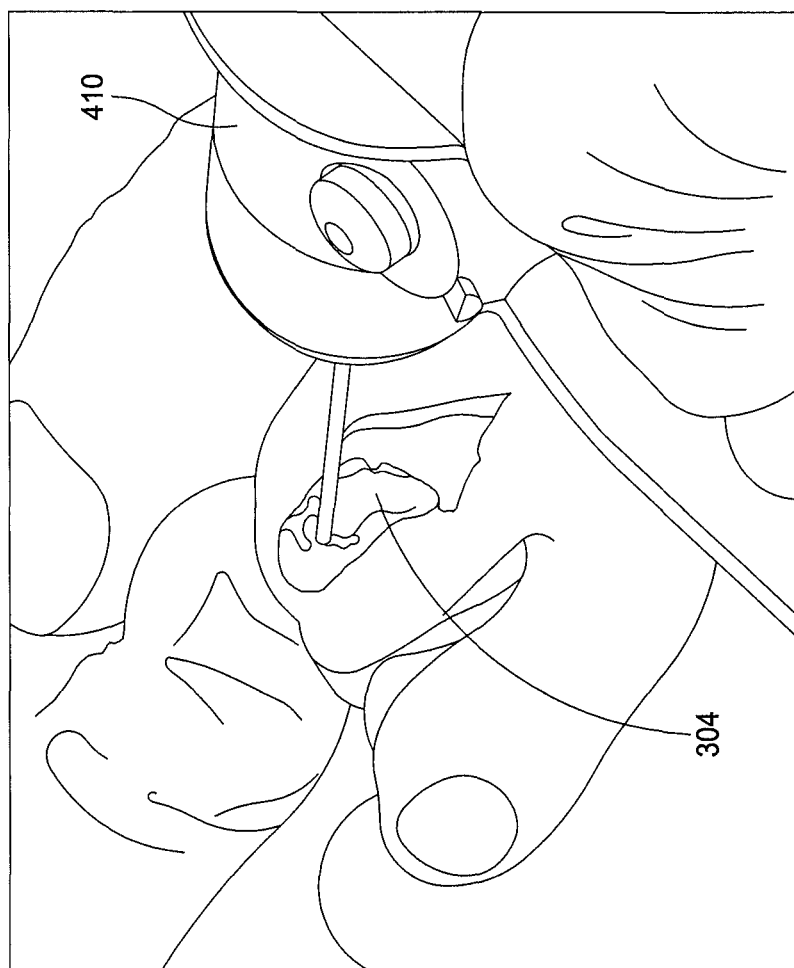


FIG. 14

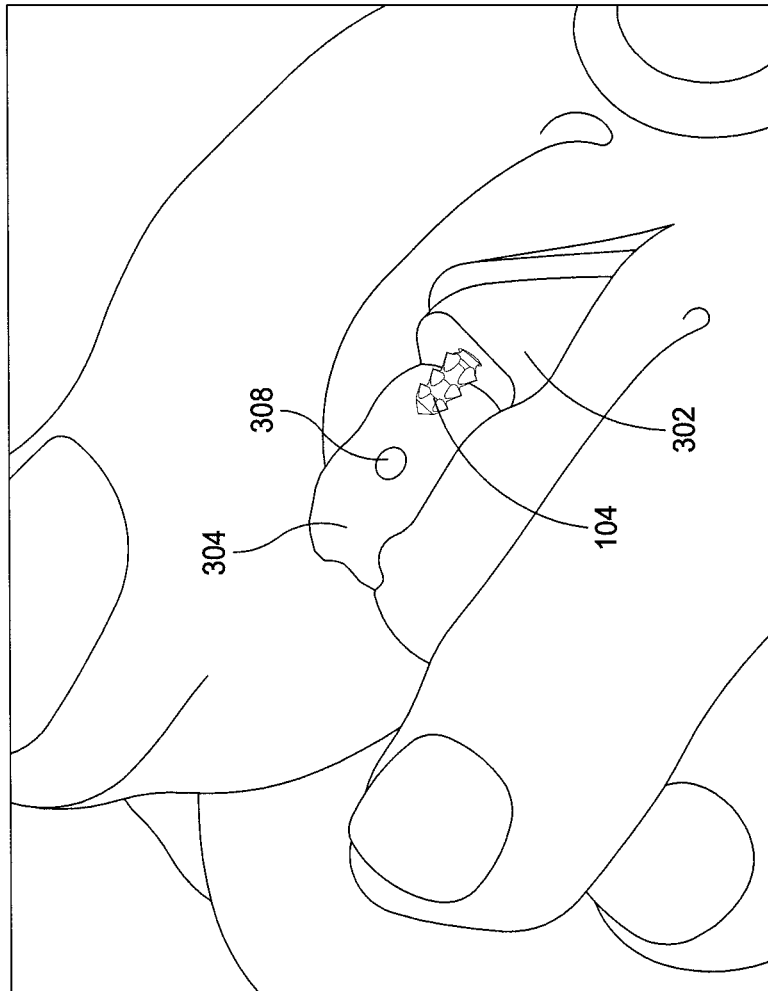
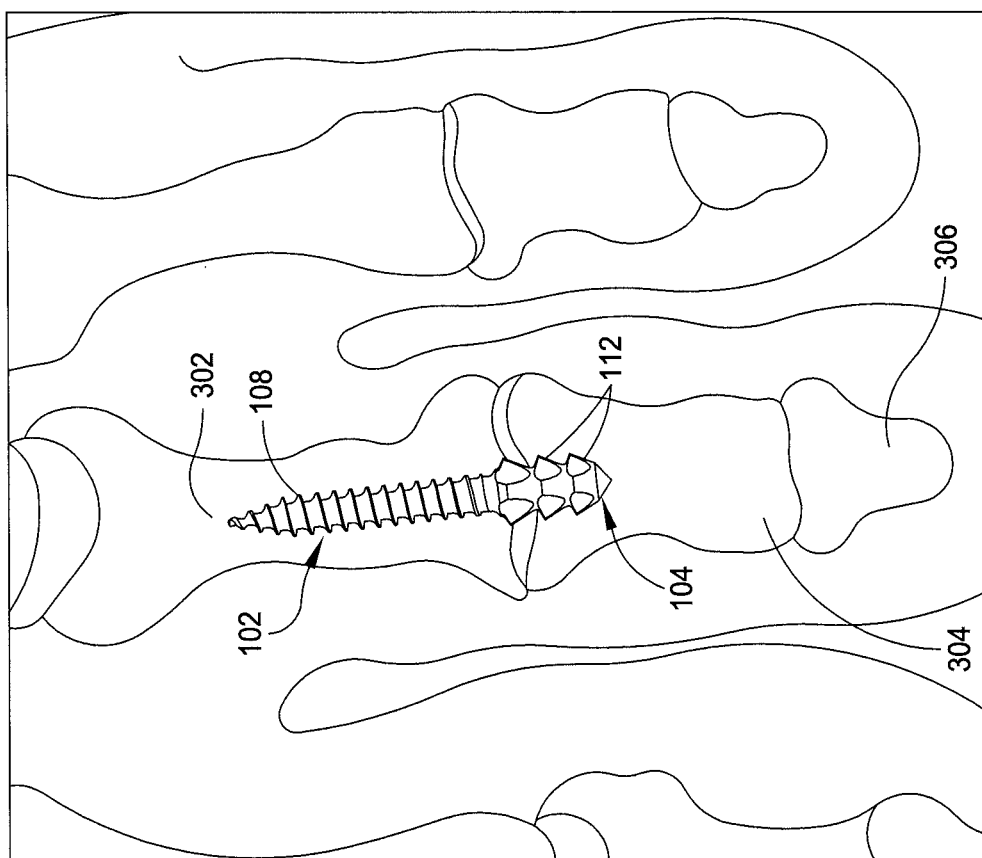


FIG. 15





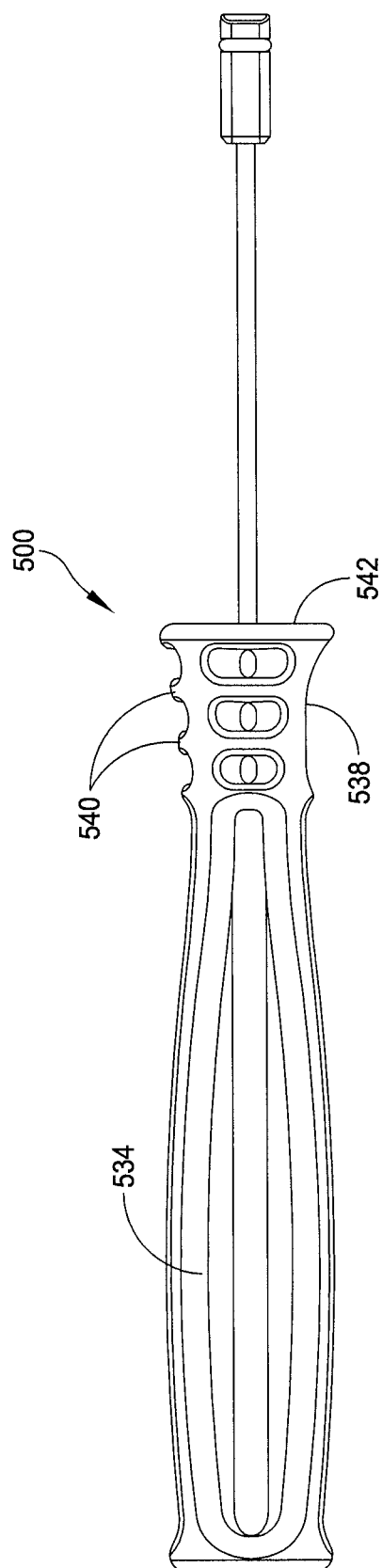


FIG. 17

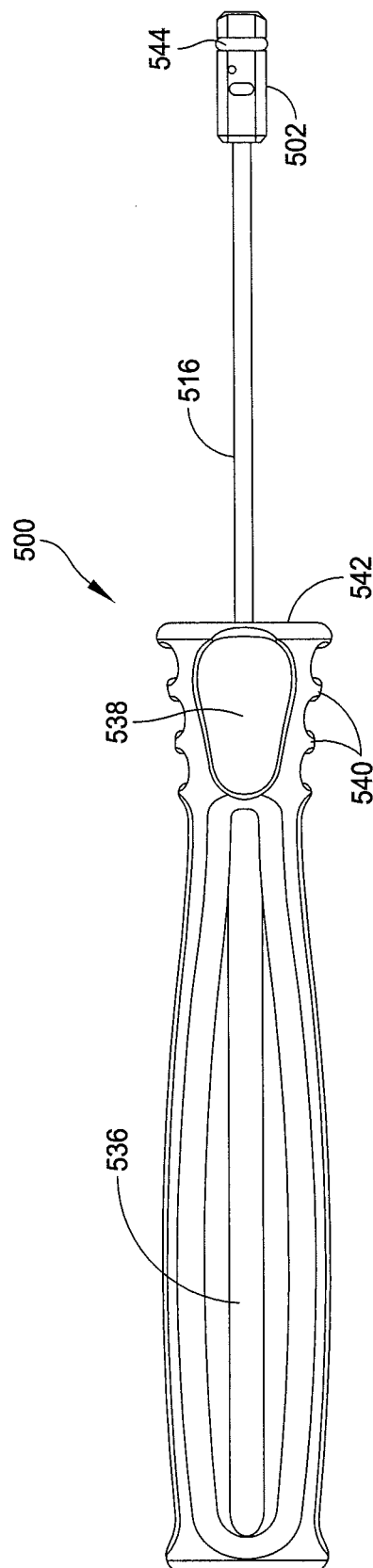


FIG. 18

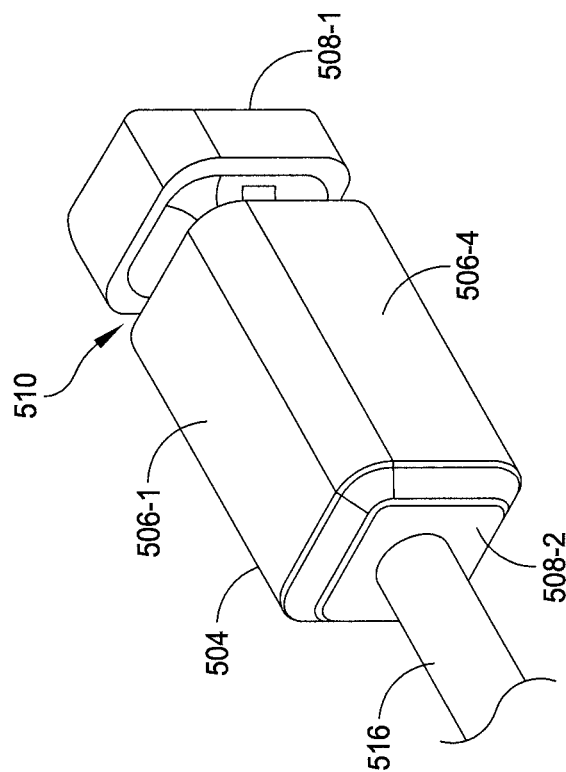


FIG. 19

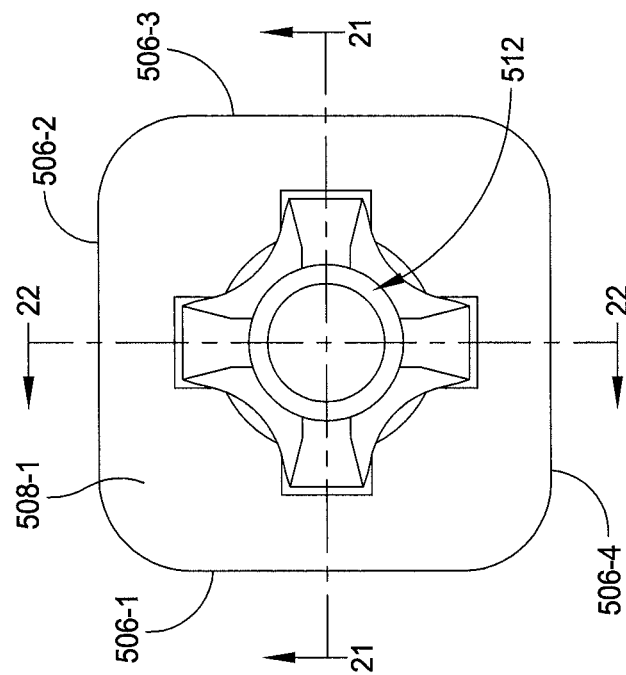


FIG. 20

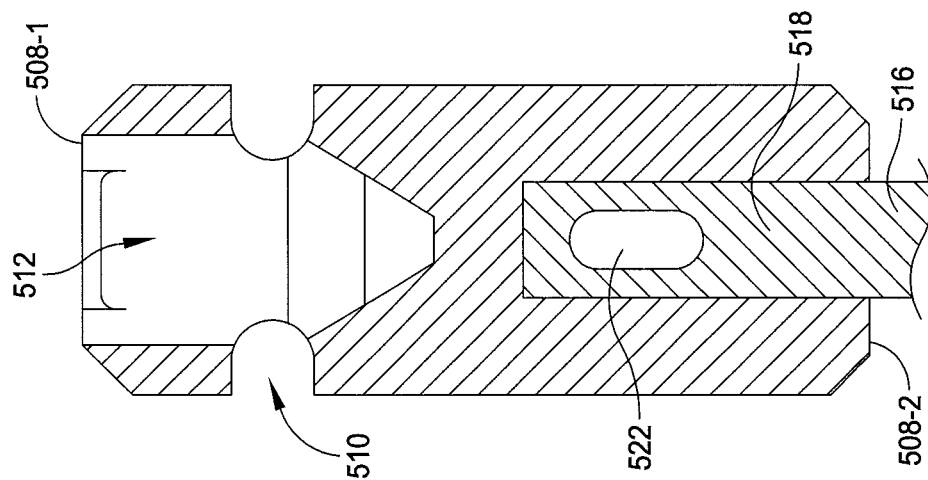


FIG. 21

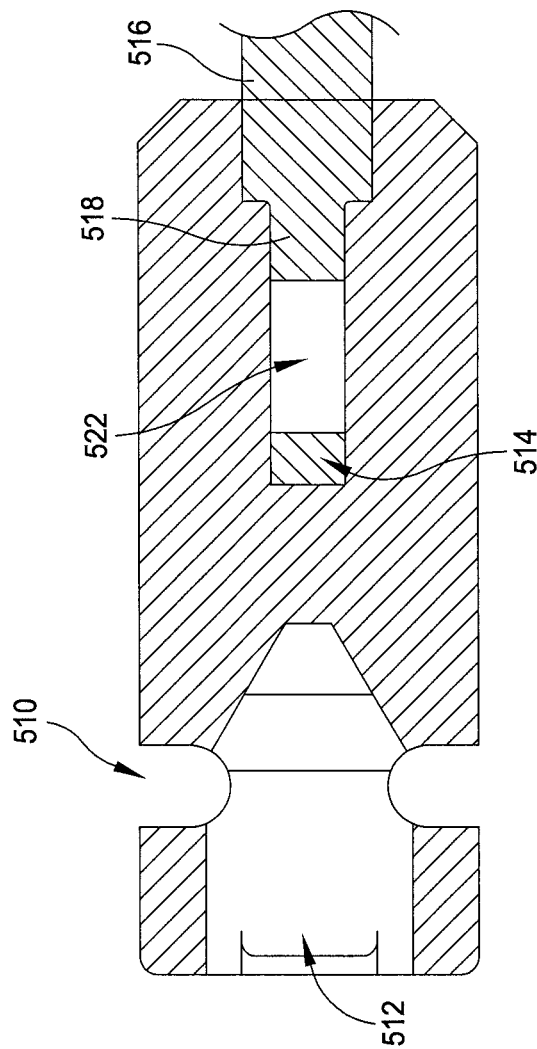


FIG. 22

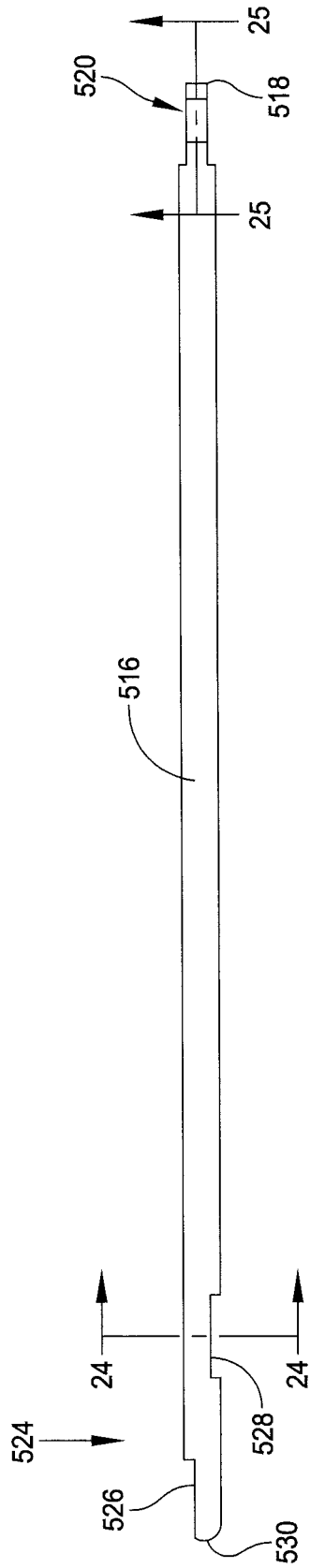


FIG. 23

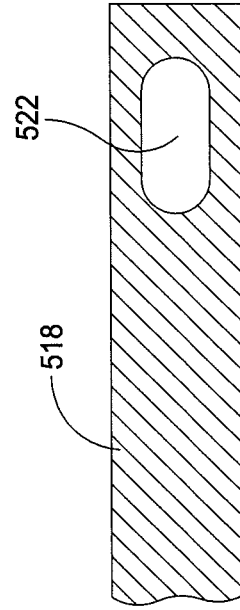


FIG. 24



FIG. 25

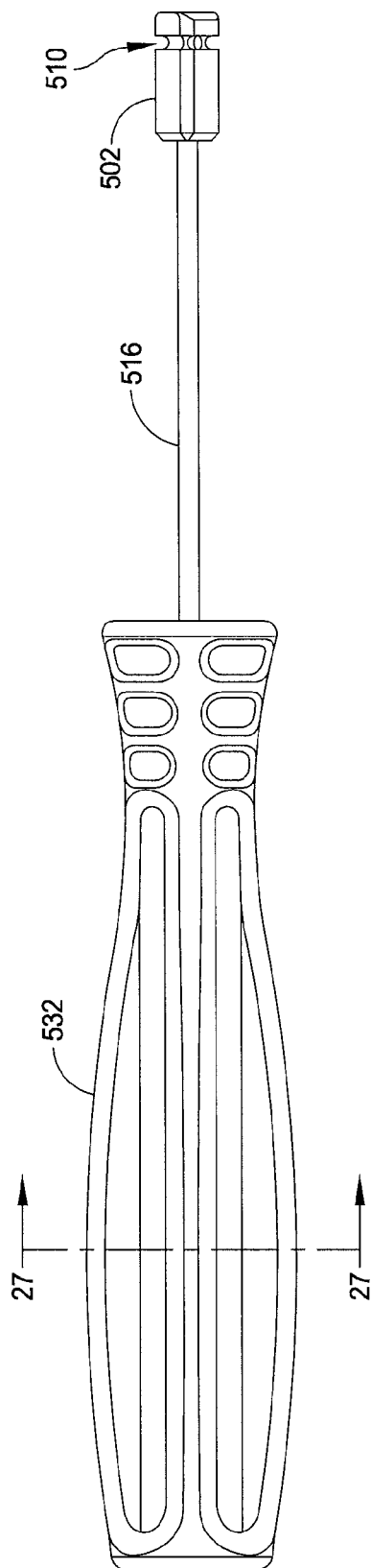


FIG. 26

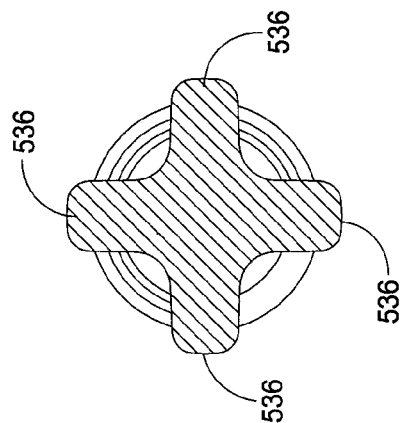


FIG. 27

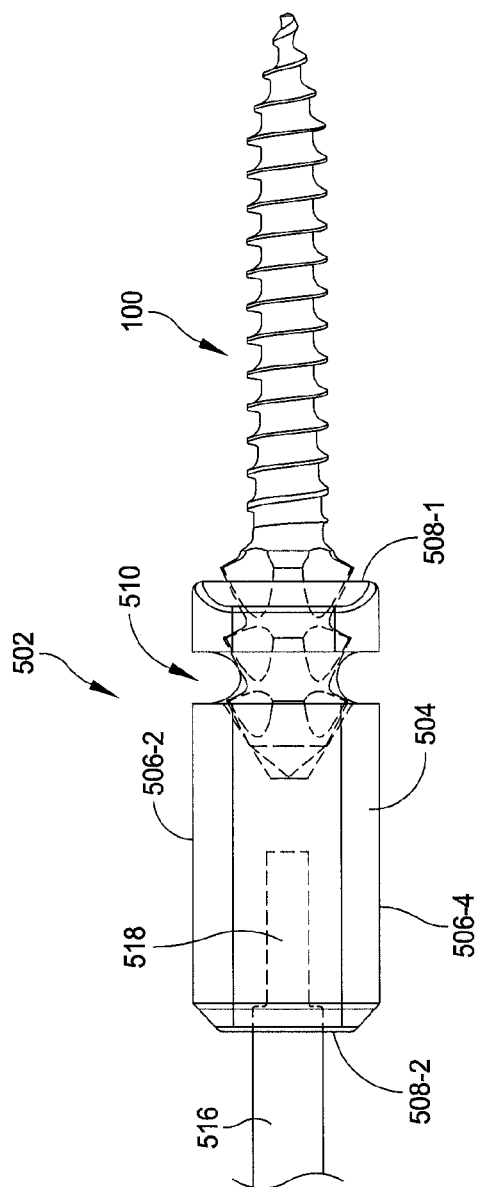


FIG. 28A

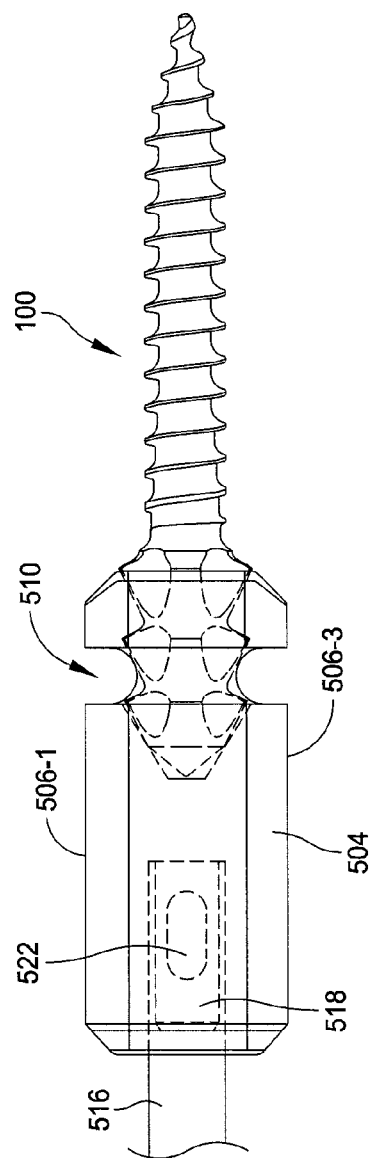


FIG. 28B

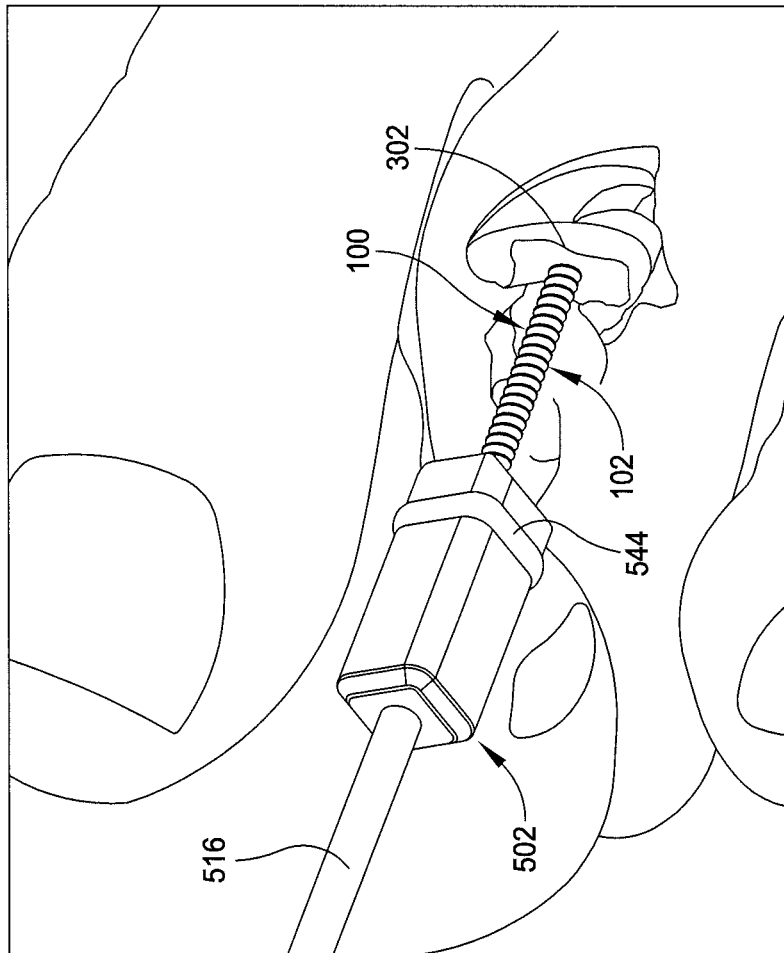


FIG. 29

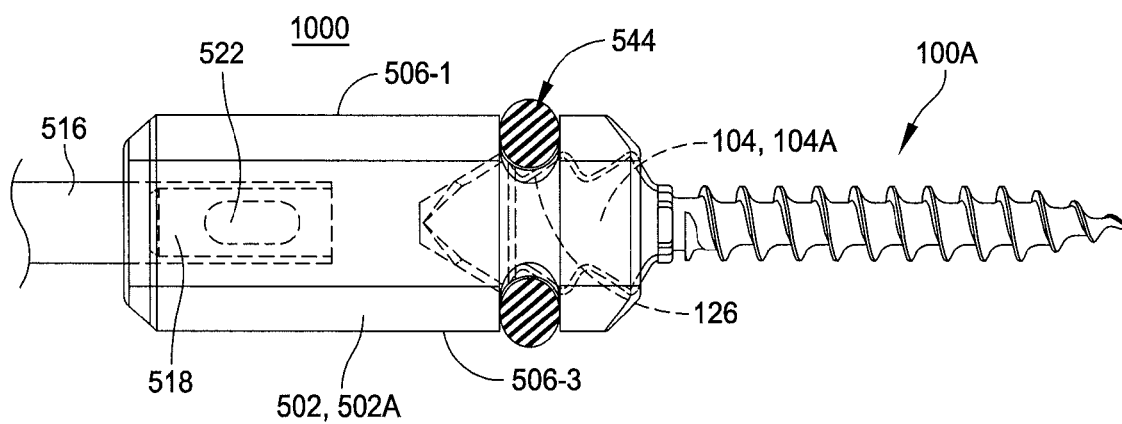
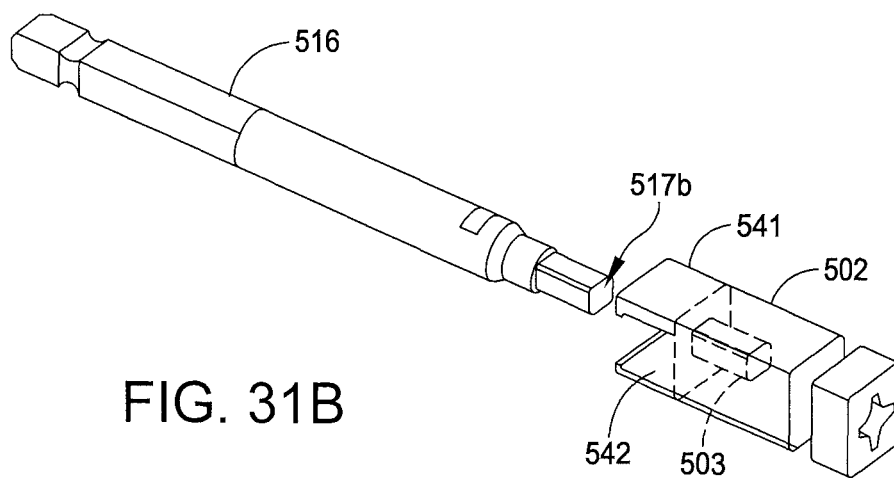
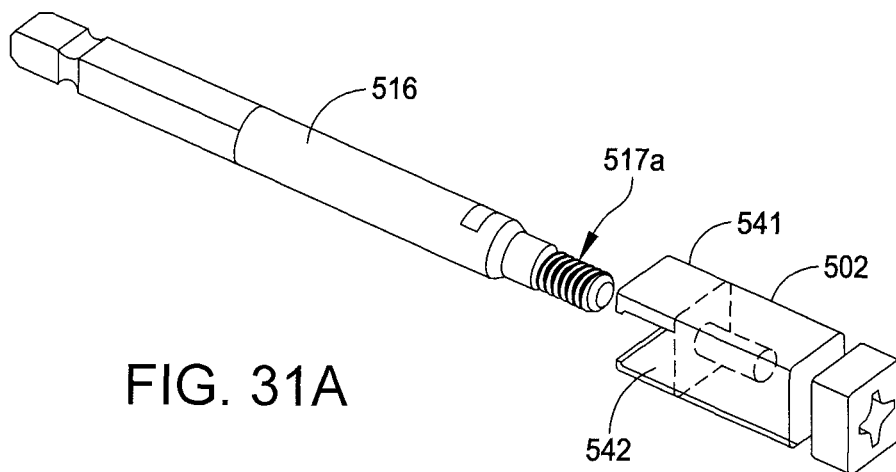


FIG. 30





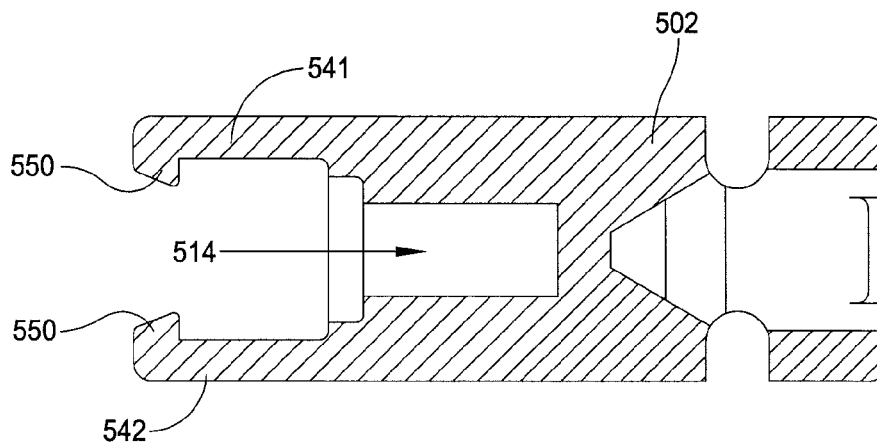


FIG. 31C

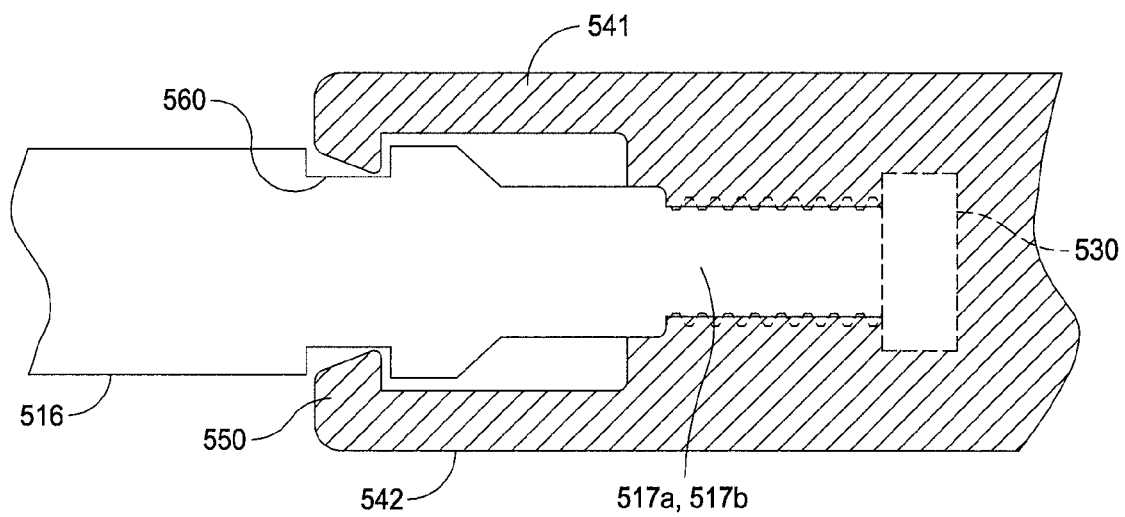


FIG. 31D

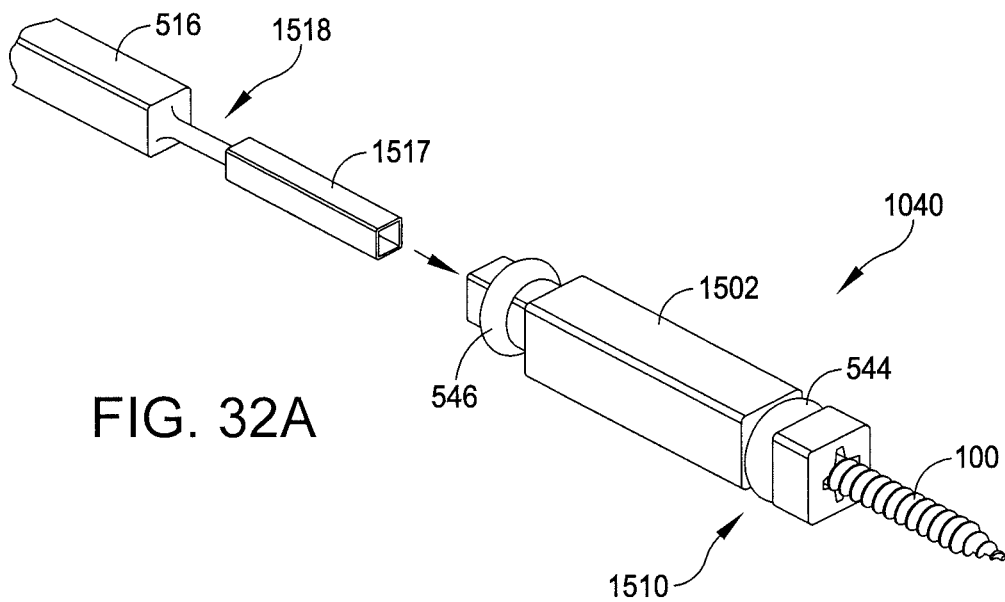


FIG. 32A

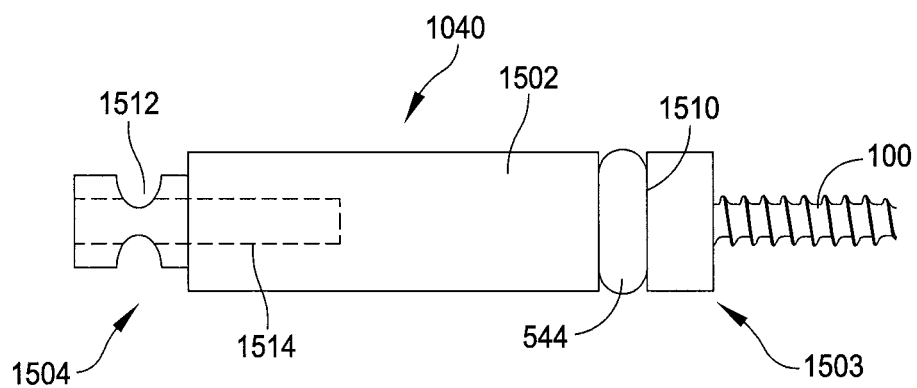


FIG. 32B

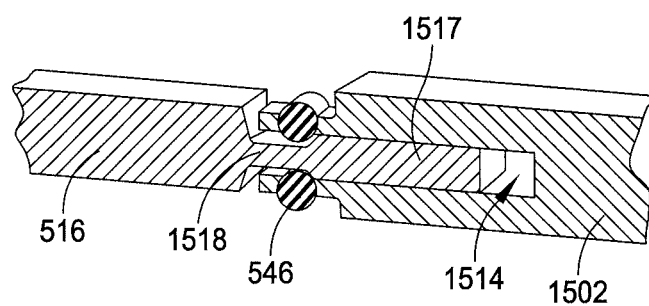


FIG. 32C

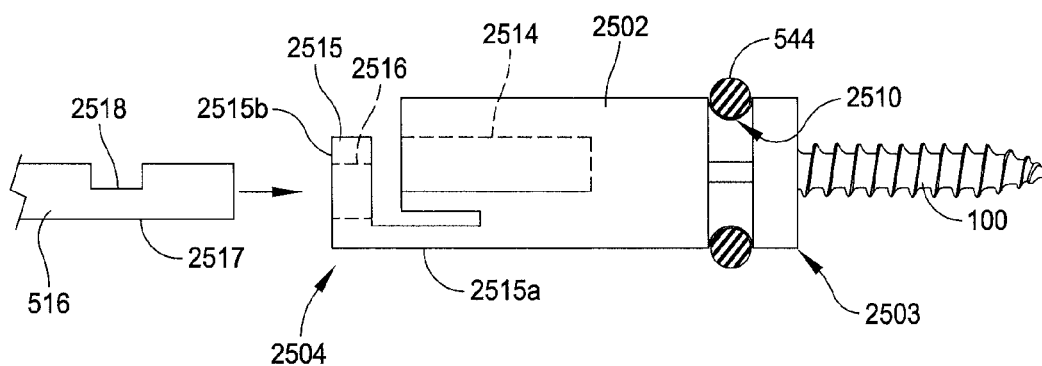


FIG. 33A

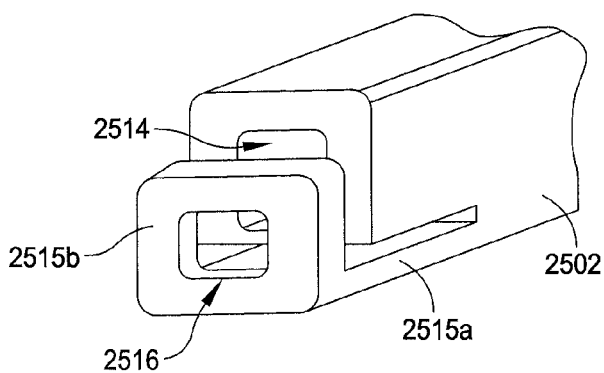


FIG. 33B

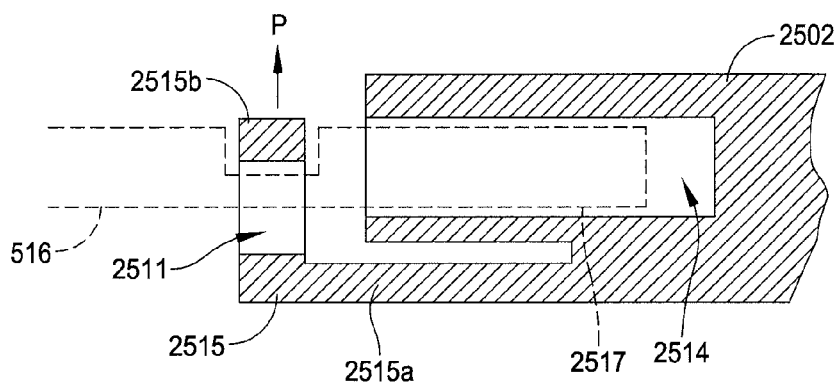


FIG. 33C

FIG. 34A

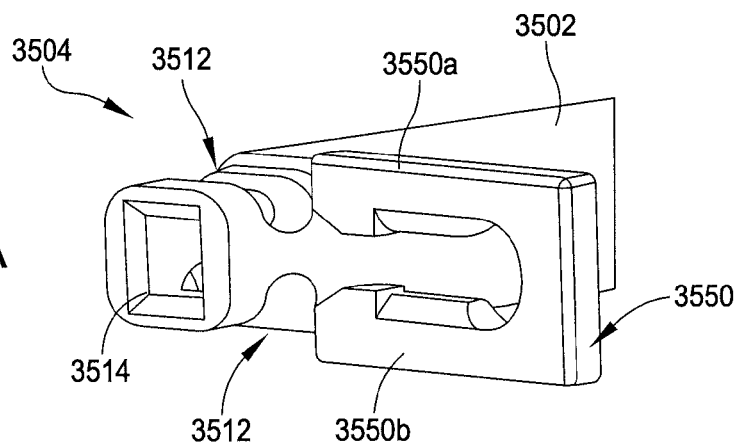


FIG. 34B

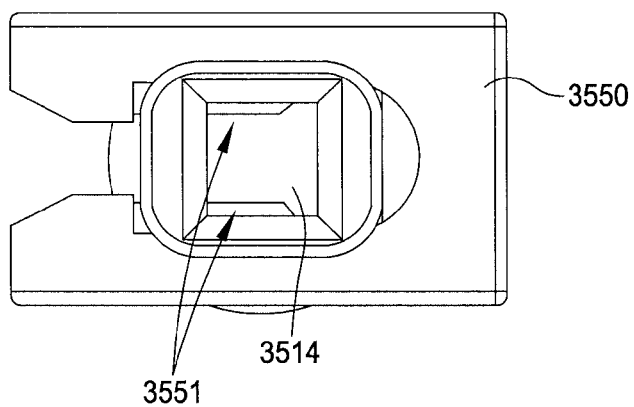
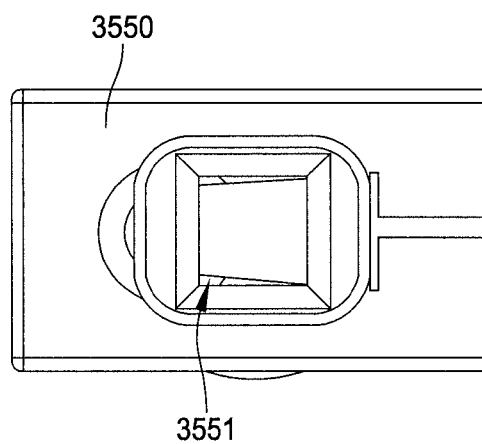


FIG. 34C



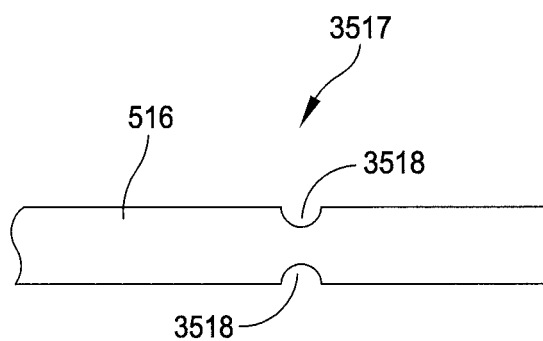


FIG. 34E

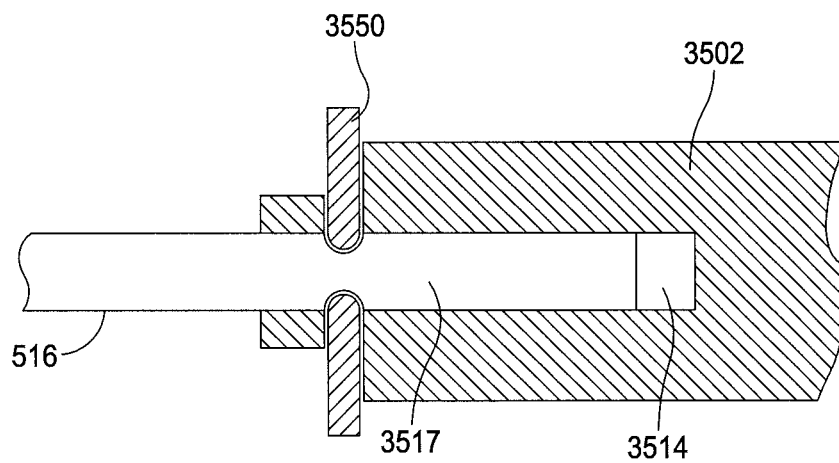


FIG. 34D

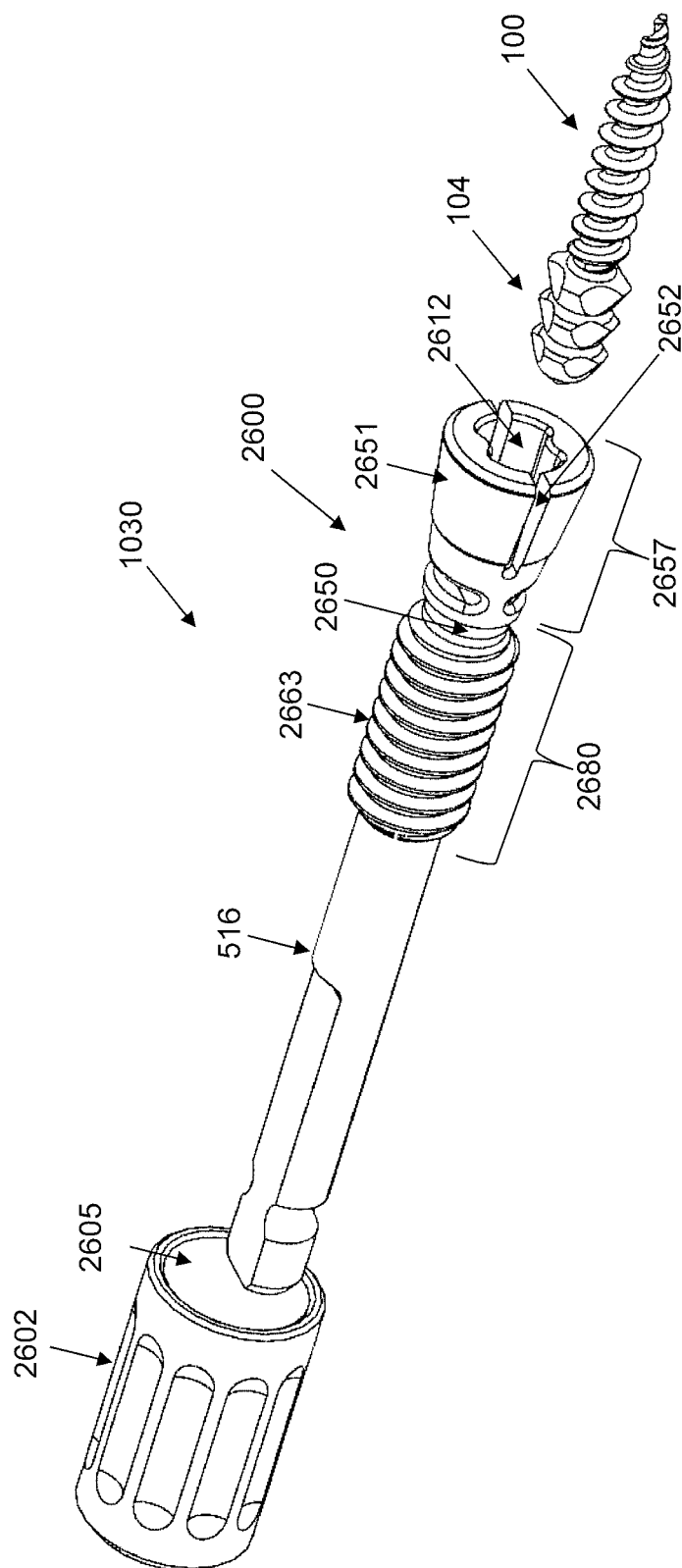


FIG. 35A

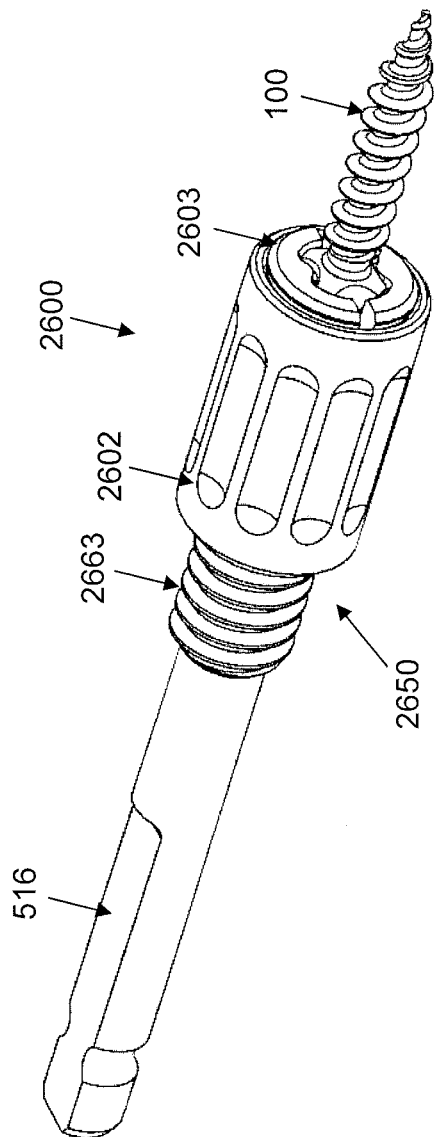


FIG. 35B

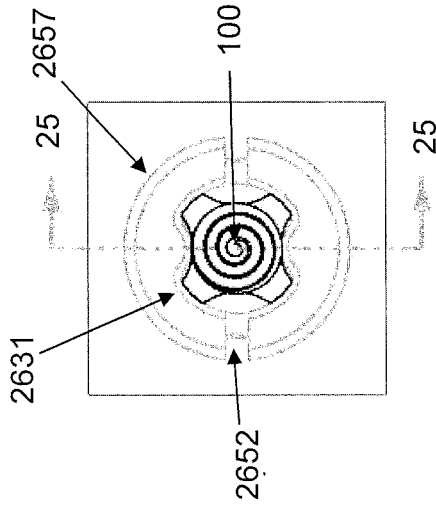


FIG. 35D

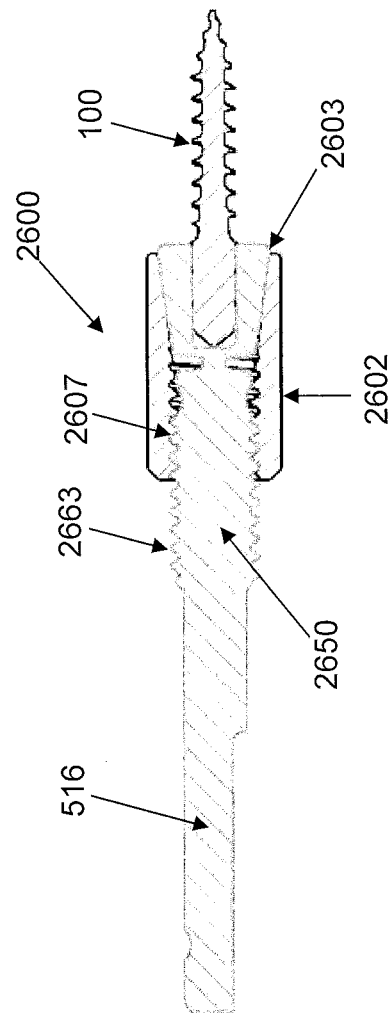


FIG. 35E



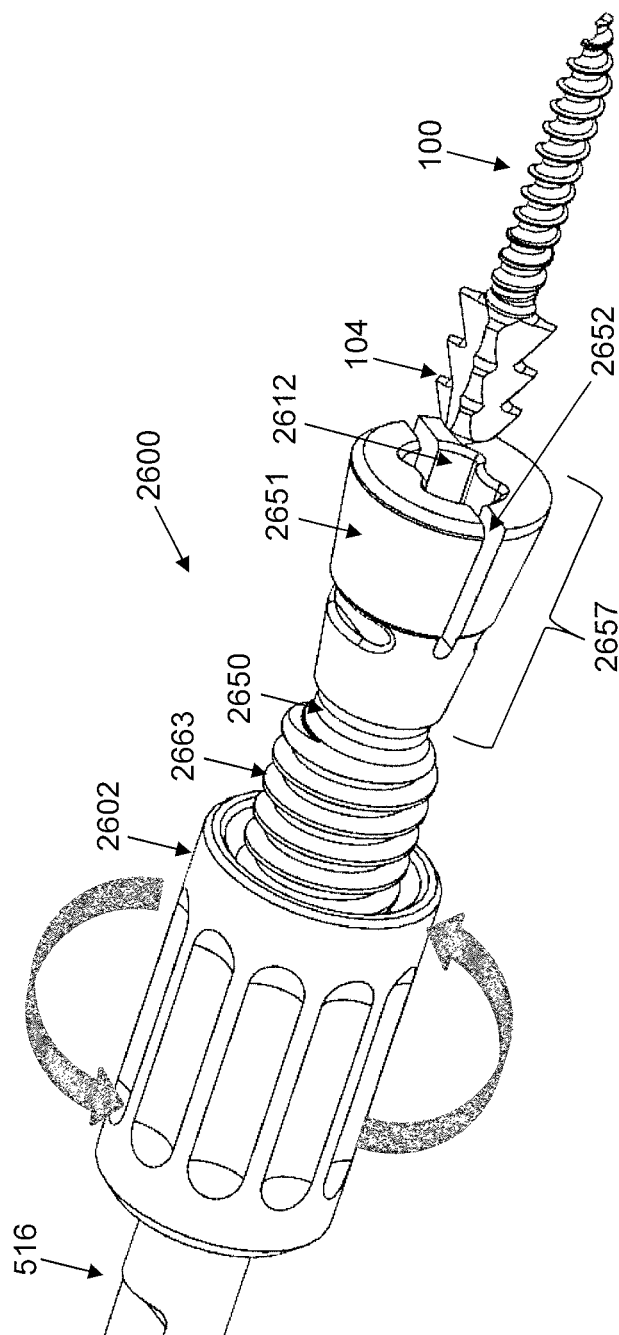


FIG. 35C

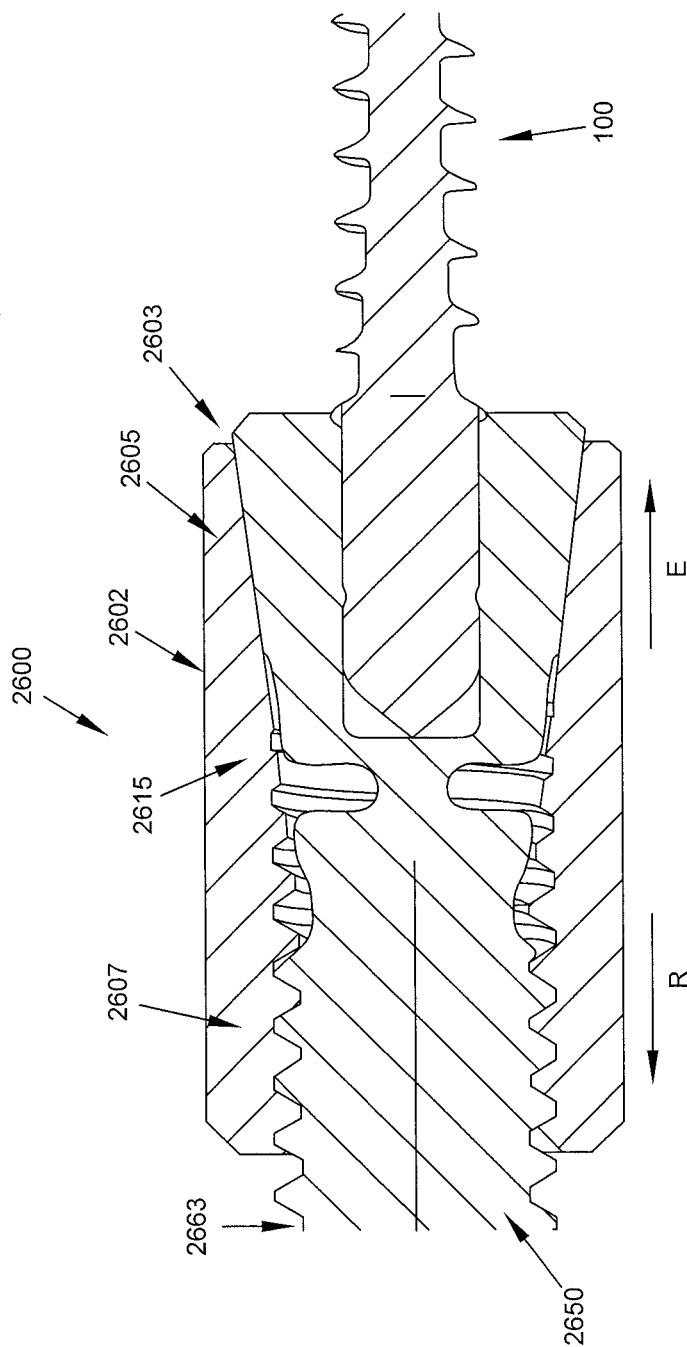


FIG. 35F

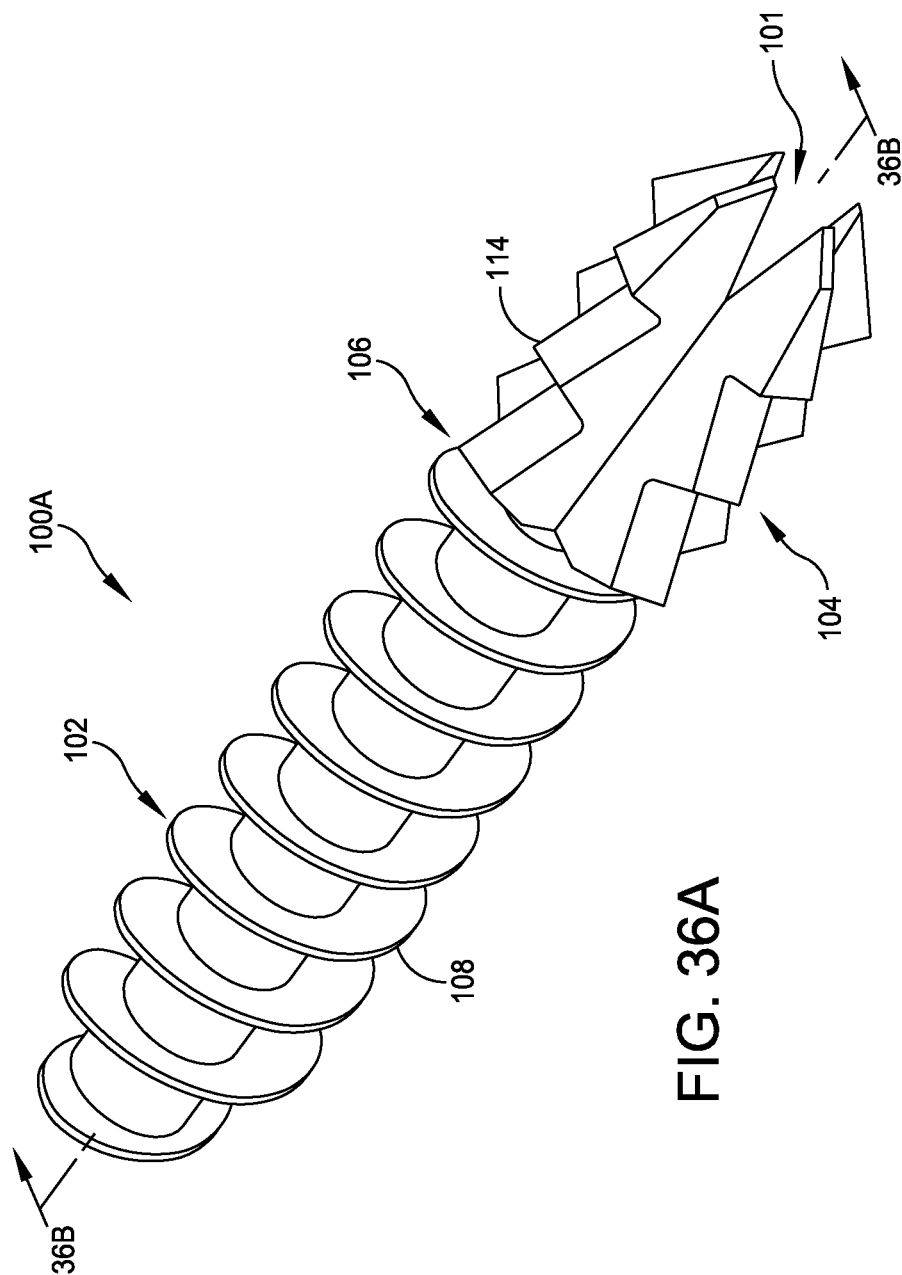


FIG. 36A

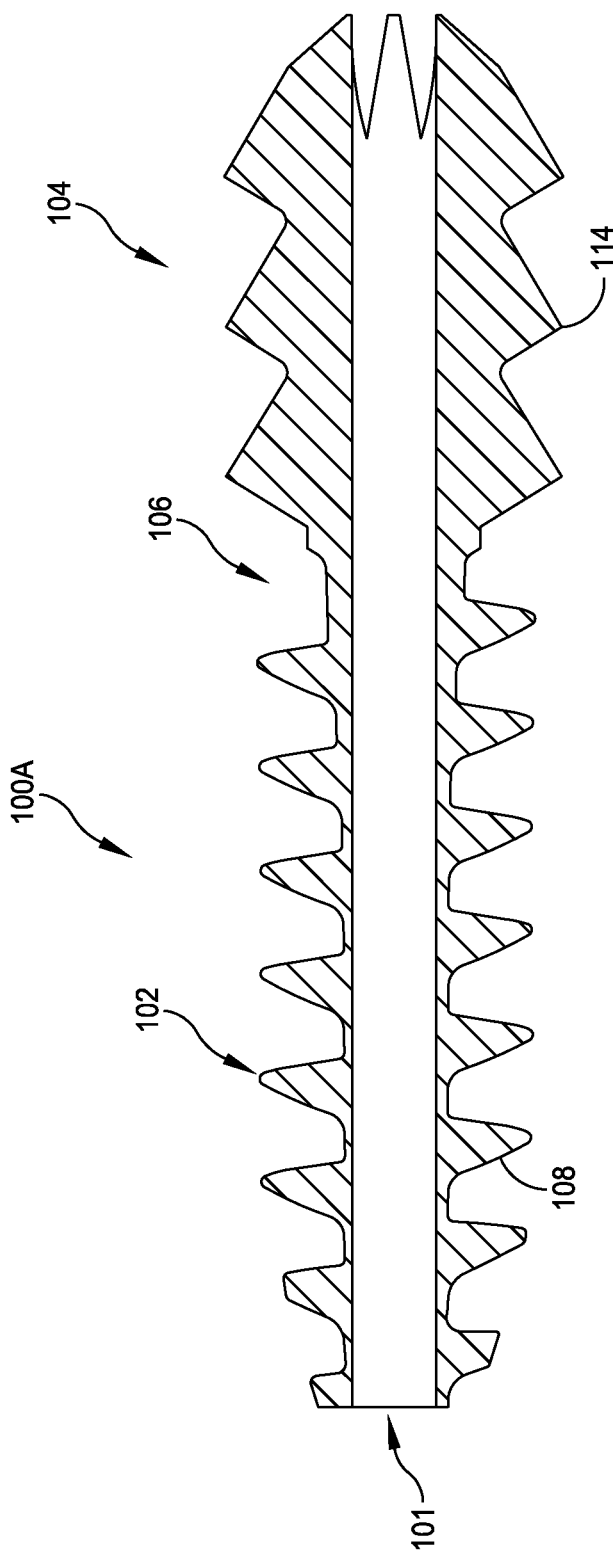


FIG. 36B

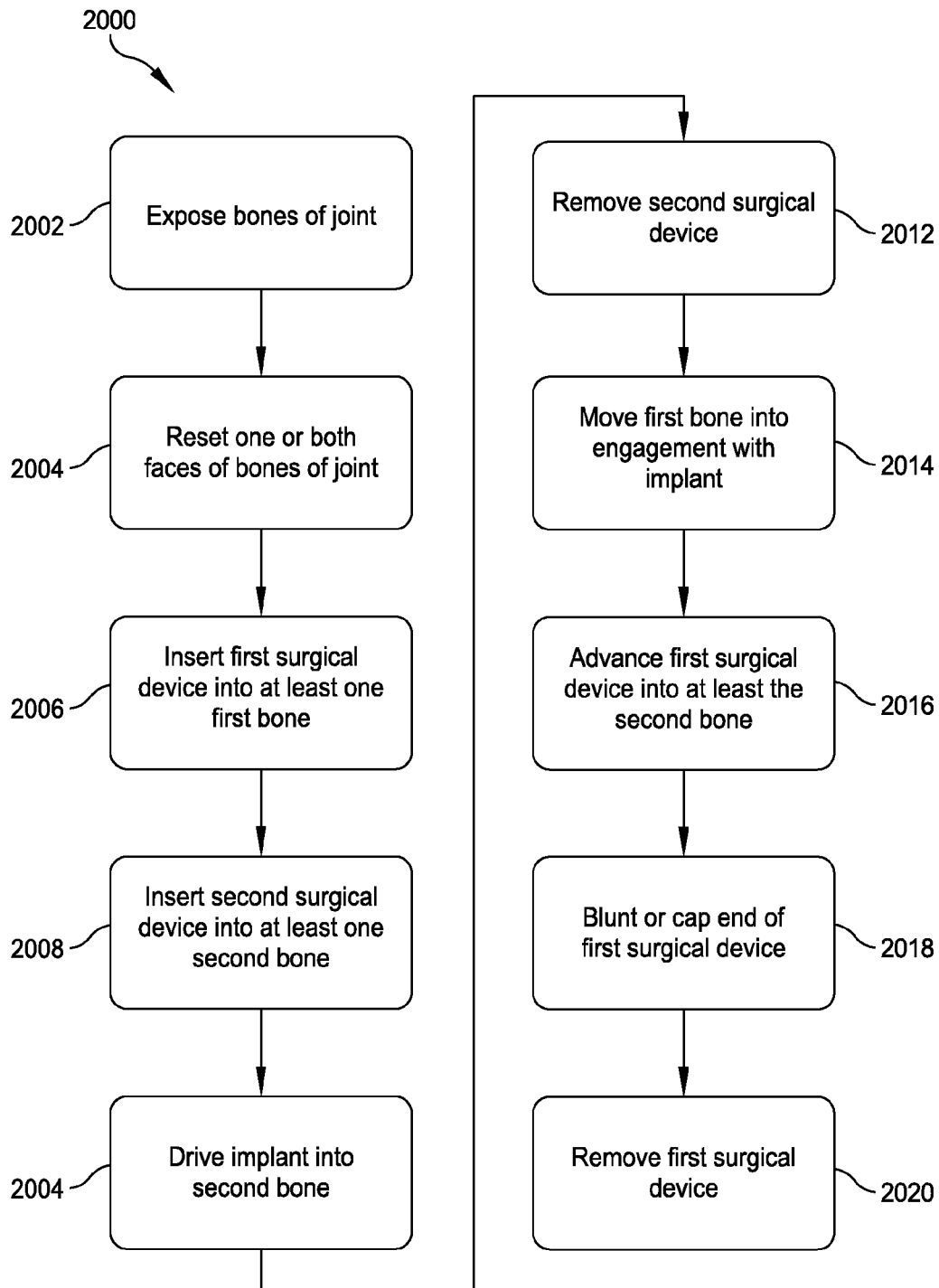


FIG. 37

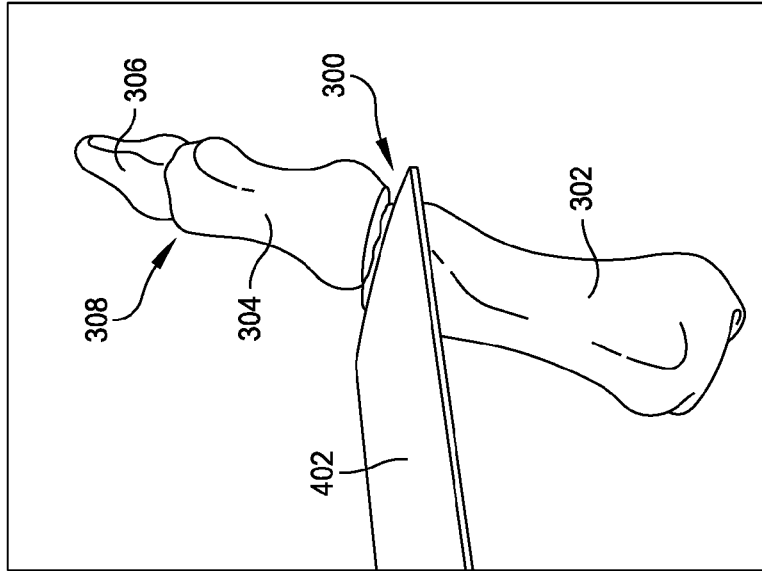


FIG. 39

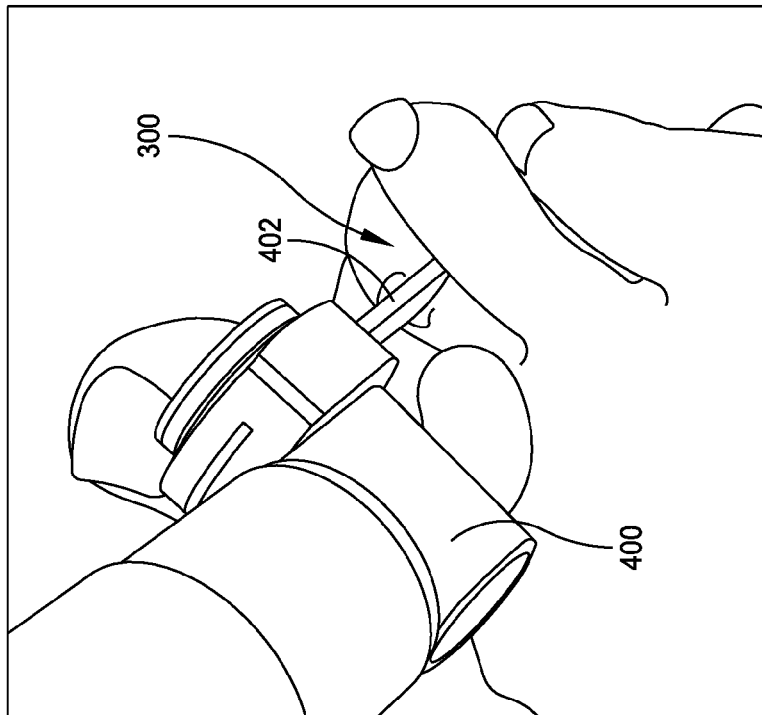
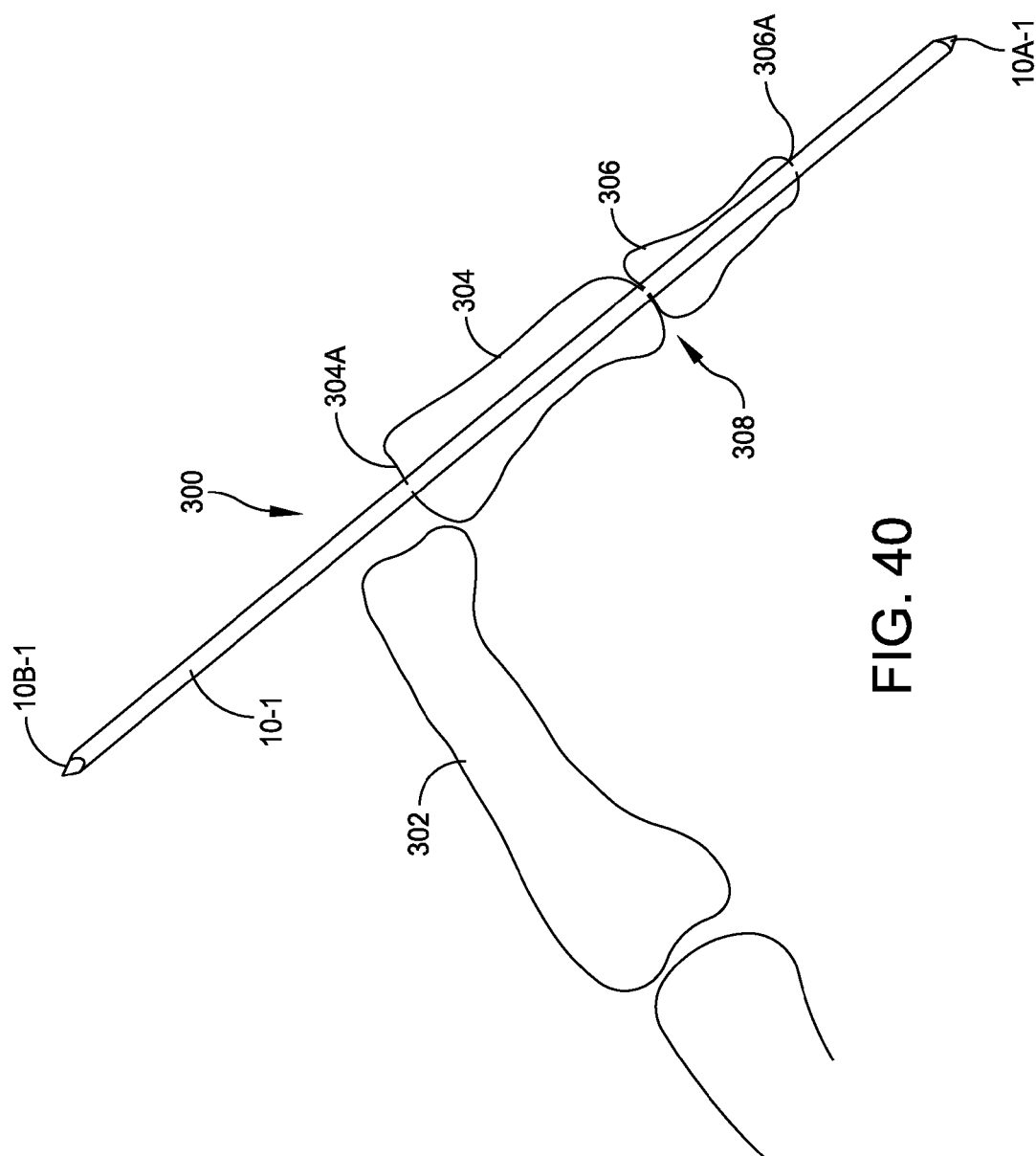
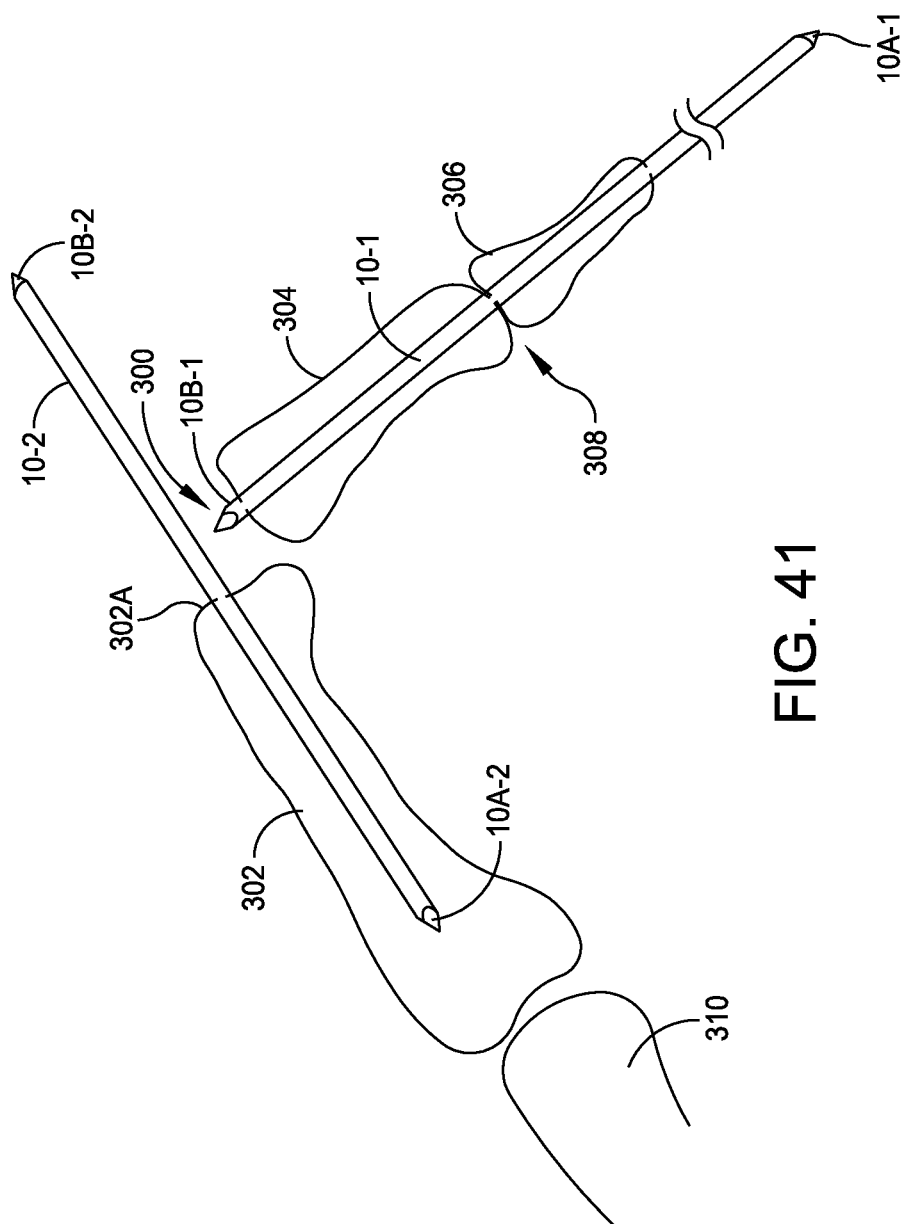


FIG. 38







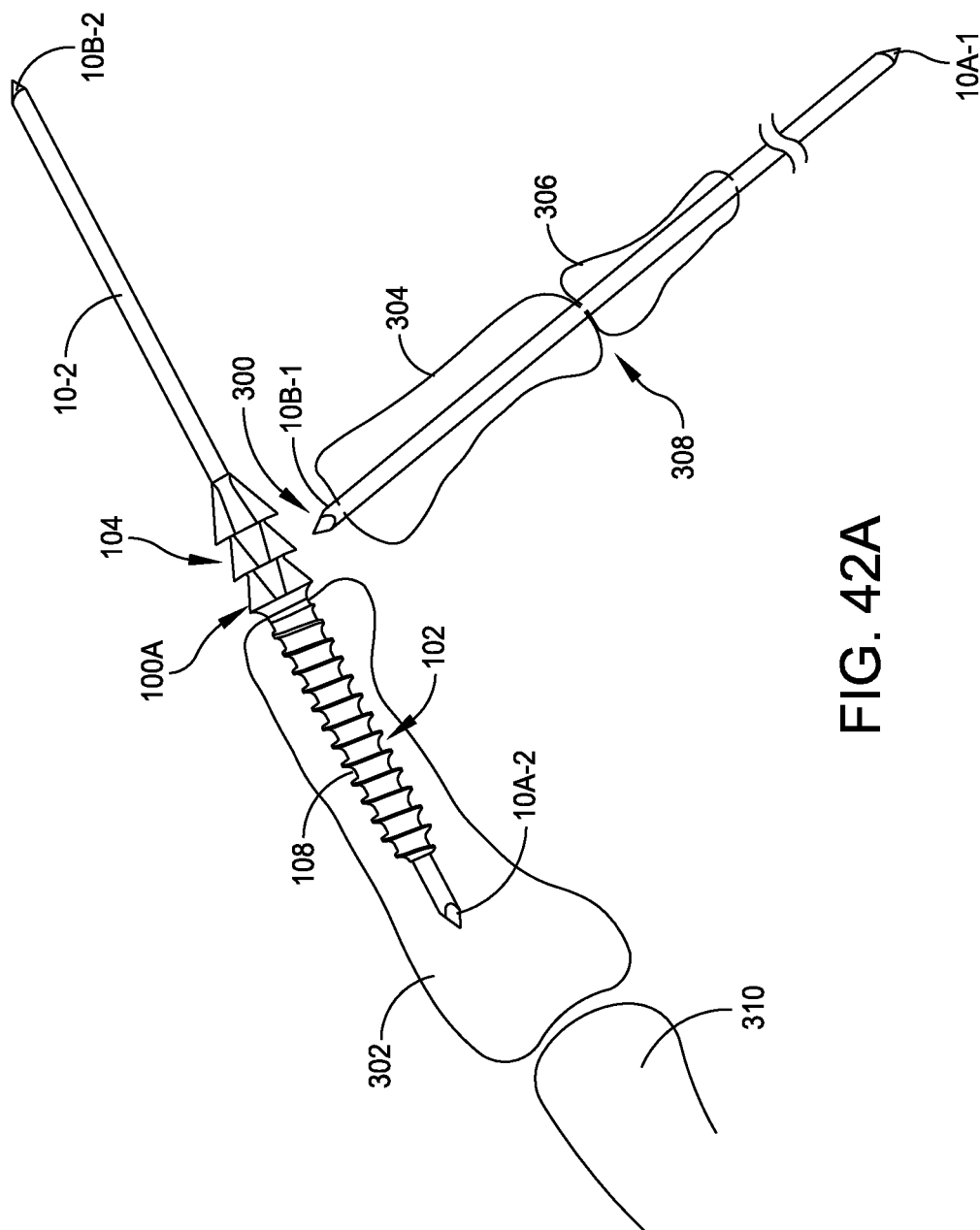


FIG. 42A

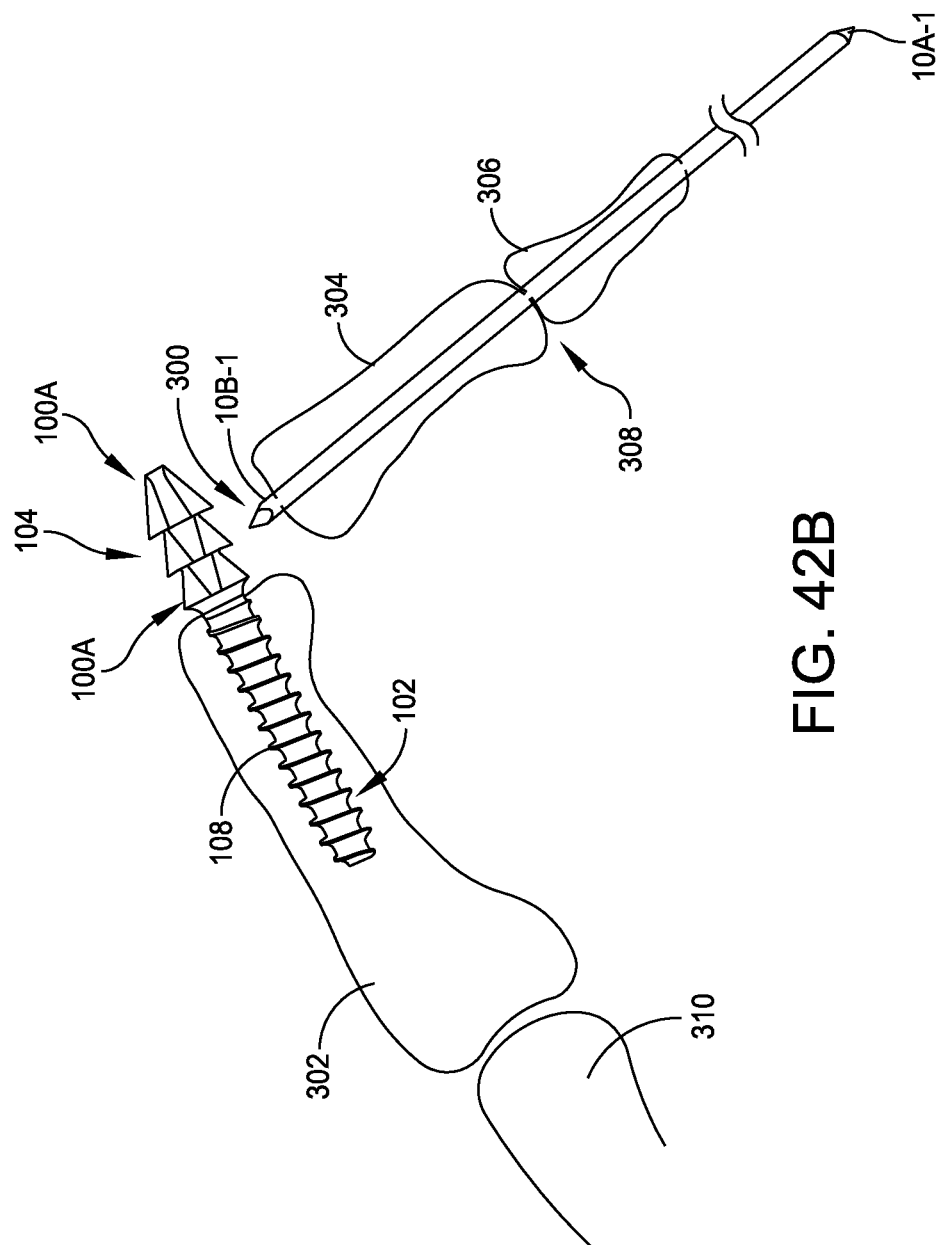


FIG. 42B

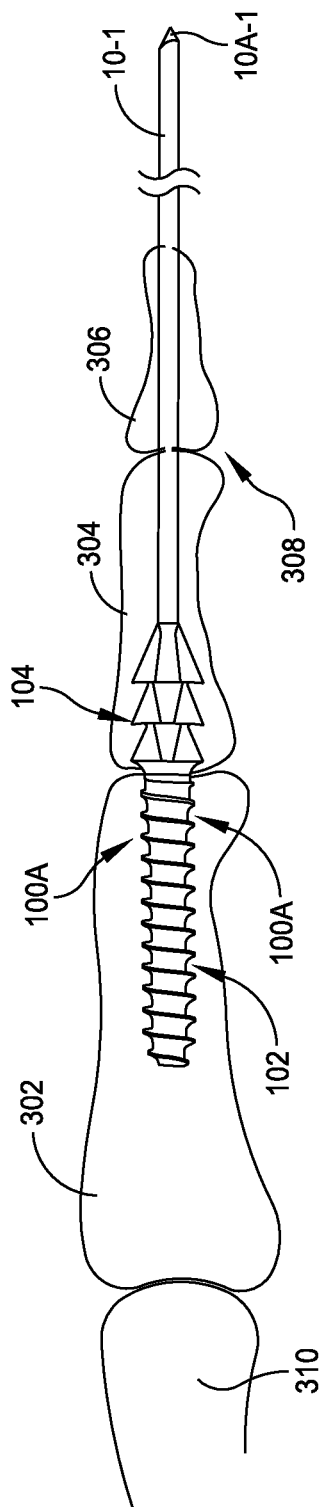


FIG. 43

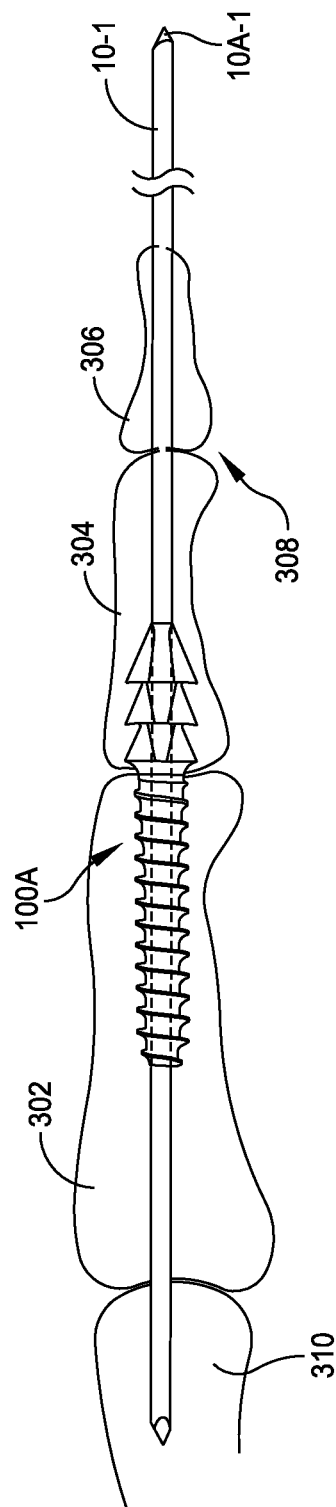


FIG. 44

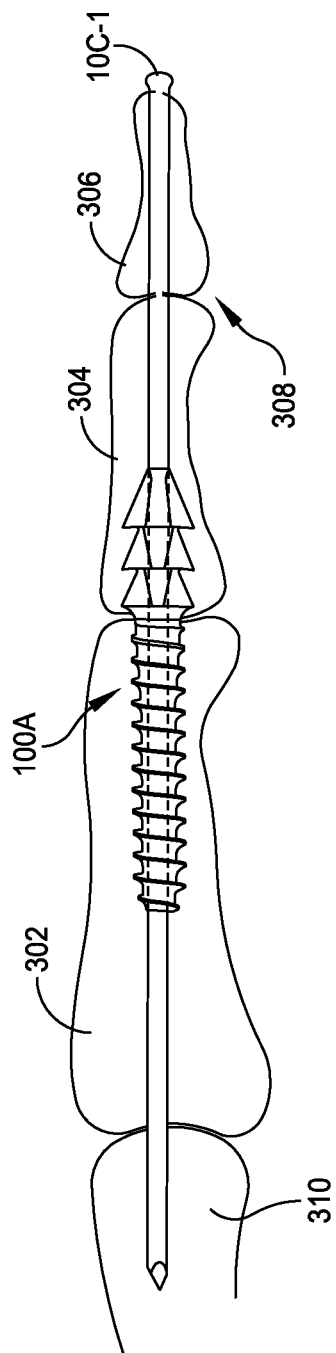


FIG. 45

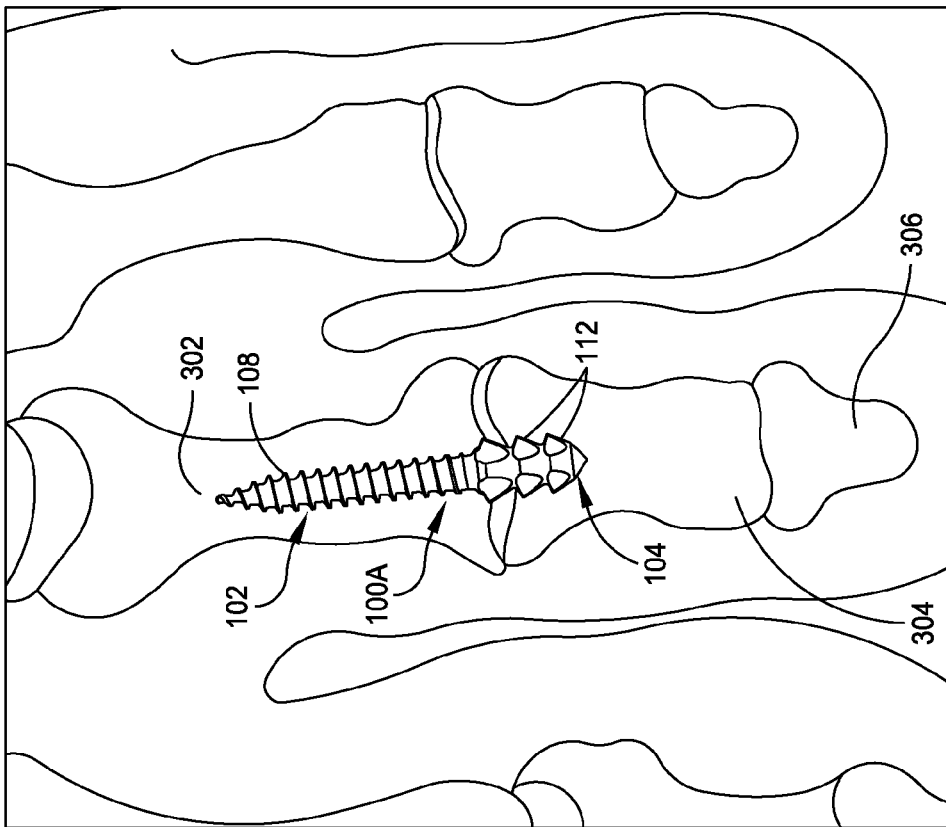


FIG. 46

1

## TWO-WIRE TECHNIQUE FOR INSTALLING HAMMERTOE IMPLANT

### FIELD OF DISCLOSURE

The disclosed system and method relate implants. More specifically, the disclosed system and method relate to installing an implant for treating hammer toe.

### BACKGROUND

Hammer toe is a deformity of the toe that affects the alignment of the bones adjacent to the proximal interphalangeal (PIP) joint. Hammer toe can cause pain and can lead to difficulty in walking or wearing shoes. A hammer toe can often result in an open sore or wound on the foot. In some instances, surgery can be required to correct the deformity by fusing one or both of the PIP and distal interphalangeal (DIP) joints.

The most common corrective surgery includes the placement of a pin or rod in the distal, middle, and proximal phalanges of the foot to fuse the PIP and DIP joints. The pin or rod is cut at the tip of the toe, externally of the body. A plastic or polymeric ball is placed over the exposed end of the rod, which remains in the foot of the patient until the PIP and/or DIP joints are fused in approximately 6 to 12 weeks. This conventional treatment has several drawbacks such as preventing the patient from wearing closed toe shoes while the rod or pin is in place, and the plastic or polymeric ball can snag a bed sheet or other object due to it extending from the tip of the toe resulting in substantial pain for the patient.

Another conventional implant includes a pair of threaded members that are disposed within adjacent bones of a patient's foot. The implants are then coupled to one another through male-female connection mechanism, which is difficult to install in situ and has a tendency to separate.

Yet another conventional implant has body including an oval head and a pair of feet, which are initially compressed. The implant is formed from nitinol and is refrigerated until it is ready to be installed. The head and feet of the implant expand due to the rising temperature of the implant to provide an outward force on the surrounding bone when installed. However, the temperature sensitive material can result in the implant deploying or expanding prior to being installed, which requires a new implant to be used.

Accordingly, an improved implant for treating hammer toe is desirable.

### SUMMARY

In some embodiments, a method includes inserting a first surgical device into an exposed first end of a first bone until a trailing end of the first surgical device is disposed adjacent to the first end of the first bone. A second surgical device is inserted into an exposed first end of a second bone while the first surgical device remains disposed within the first bone. A first portion of an implant is advanced into the second bone while being engaged with a passageway defined by the implant such that the implant is guided by the second surgical device. The second surgical device is removed from the second bone and from its engagement with the implant. The first bone is repositioned such that the first surgical device is aligned with the passageway defined by the implant, and the first bone is forced into engagement with a second portion of the implant.

In some embodiments, a method includes forming an incision to gain access to a joint between first and second

2

bones, flexing the first and second bones such that the first and second bones are disposed at an angle with respect to one another, inserting a first surgical device into the first bone until a first end of the first surgical device is disposed adjacent to a first end of the first bone, and inserting a second surgical device into the second bone while the first surgical device remains disposed within the first bone. A first portion of an implant is advanced into the second bone while a passageway defined by the implant is engaged with the second surgical device such that the implant is guided by the second surgical device. The second surgical device is removed from the second bone and from its engagement with the implant. The first bone is repositioned such that the first surgical device is aligned with the passageway defined by the defined by the implant, and the first bone is forced into engagement with a second portion of the implant.

In some embodiments, a surgical method includes gaining access to a joint between a middle phalange and a proximal phalange, inserting a first end of a first surgical device into a proximal end of the middle phalange, advancing the first surgical device into the middle phalange and a distal phalange until a second end of the first surgical device is disposed adjacent to the proximal end of the middle phalange, and inserting a first end of a second surgical device into a distal end of the proximal phalange while the first surgical device remains disposed within the middle and distal phalanges. A first portion of an implant is advanced into the proximal phalange using the second surgical device as a guide. The second implant is removed. The first surgical device is inserted into a passageway defined by the implant while the first surgical device remains disposed within the middle and distal phalange, and the first surgical device is removed from its engagement with the implant, middle phalange, and distal phalange.

### BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be more fully disclosed in, or rendered obvious by the following detailed description of the preferred embodiments of the invention, which are to be considered together with the accompanying drawings wherein like numbers refer to like parts and further wherein:

FIG. 1 is an isometric view of an improved hammer toe implant according to some embodiments;

FIG. 2 is a top side view of the hammer toe implant illustrated in FIG. 1;

FIG. 3 is a top side view of the blade portion of the hammer toe implant illustrated in FIG. 6;

FIG. 4 is a sectional view of the hammer toe implant taken along line 3-3 in FIG. 2;

FIG. 5 is an end on view of the hammer toe implant taken along line 4-4 in FIG. 2;

FIG. 6 is an isometric view of an improved, cannulated hammer toe implant according to some embodiments;

FIG. 7 is a side view of one example of a driving adapter for use with the hammer toe implants illustrated in FIGS. 1 and 6;

FIG. 8 is an end view of the driving adapter illustrated in FIG. 7;

FIG. 9 is a side view of another example of a driving adapter for use with the hammer toe implants illustrated in FIGS. 1 and 6;

FIG. 10 is an end view of the driving adapter illustrated in FIG. 9;

FIG. 11A is an assembly view of a hammer toe implant engaged by a driving adapter;

FIG. 11B is an assembly view of a cannulated hammer toe implant engaged by a cannulated driving adapter;

FIG. 12A illustrates the middle and proximal phalangees of a foot being resected;

FIG. 12B illustrates the middle and proximal phalangees of a foot being resected;

FIG. 13 illustrates a hammer toe implant being driven into a proximal phalange;

FIG. 14 illustrates a middle phalange being drilled or broached;

FIG. 15 illustrates a blade of a hammer toe implant extending from the proximal phalange with the middle phalange having been drilled or broached;

FIG. 16 illustrates a hammer toe implant installed in the middle and proximal phalangees;

FIG. 17 illustrates another example of a driving assembly for installing an implant;

FIG. 18 illustrates a side view of the driving assembly illustrated in FIG. 17;

FIG. 19 is an isometric view of an adapter of the driving assembly illustrated in FIG. 17;

FIG. 20 is an end view of the adapter illustrated in FIG. 19;

FIG. 21 is a cross-sectional view of the adapter taken along line 21-21 in FIG. 20;

FIG. 22 is a cross-sectional view of the adapter taken along line 22-22 in FIG. 20;

FIG. 23 is a plan view of the driving rod of the driving assembly illustrated in FIG. 17;

FIG. 24 is a cross-sectional view of the driving rod taken along line 24-24 in FIG. 23;

FIG. 25 is a cross-sectional view of the fin of the driving rod taken along line 25-25 in FIG. 23;

FIG. 26 is a plan view of driving assembly illustrated in FIG. 17 without the o-ring;

FIG. 27 is a cross-sectional view of the handle taken along line 27-27 in FIG. 26;

FIG. 28A illustrates an implant coupled to the adapter of the driving assembly illustrated in FIG. 17;

FIG. 28B illustrates an implant coupled to the adapter of the driving assembly illustrated in FIG. 17;

FIG. 29 illustrates a hammer toe implant being driven into a proximal phalange;

FIG. 30 illustrates an implant kit comprising a hammer toe implant preloaded in the adapter shown in FIGS. 19-22;

FIG. 31A is an isometric view of an implant kit according to some embodiments whose adapter has an implant receiving end configured to couple to an implant by an O-ring according to the adapter of FIGS. 19, 28A and 28B and having a driver shaft coupling end configured for coupling to the driver shaft by mating male and female threads;

FIG. 31B is an isometric view of an implant kit according to some embodiments whose adapter has an implant receiving end configured to couple to an implant by an O-ring according to the adapter of FIGS. 19, 28A and 28B and having a driver shaft coupling end configured for coupling to the driver shaft by a pair of opposing tabs;

FIG. 31C is a cross-sectional view of an adapter having a driver shaft coupling end illustrated in FIG. 31B and an implant receiving end according to some embodiments;

FIG. 31D is a cross-sectional view of an adapter having a driver shaft coupling end illustrated in FIG. 31A according to some embodiments;

FIG. 32A is an isometric view of an implant kit according to some embodiments whose adapter has an implant receiving end configured to couple to an implant by an O-ring according to the adapter of FIGS. 19, 28A and 28B and

having a driver shaft coupling end configured for coupling to the driver shaft by an O-ring;

FIG. 32B is a side view of an adapter has an implant receiving end configured to couple to an implant by an O-ring according to the adapter of FIGS. 19, 28A and 28B and having a driver shaft coupling end configured for coupling to the driver shaft by an O-ring according to some embodiments;

FIG. 32C is a cross-sectional view of an implant kit whose adapter has a driver shaft coupling end for coupling to the driver shaft by an O-ring according to some embodiments;

FIG. 33A is a side view of an implant kit according to some embodiments whose adapter has an implant receiving end configured to couple to an implant by an O-ring according to the adapter of FIGS. 19, 28A and 28B and having a driver shaft coupling end configured for coupling to the driver shaft by an off-set clip;

FIG. 33B is an end perspective view of an adapter having a driver shaft coupling end configured for coupling to the driver shaft by an off-set clip according to some embodiments;

FIG. 33C is a cross-sectional view of an adapter having a driver shaft coupling end configured for coupling to the driver shaft by an off-set clip according to some embodiments;

FIG. 34A is an end perspective view of an adapter having a driver shaft coupling end configured for coupling to the driver shaft by a C-clip according to some embodiments;

FIG. 34B is an end view of an adapter having a driver shaft coupling end configured for coupling to the driver shaft by a C-clip according to some embodiments;

FIG. 34C is an end view of an adapter having a driver shaft coupling end configured for coupling to the driver shaft by a C-clip according to some embodiments;

FIG. 34D is cross-sectional view of an implant kit according to some embodiments having a driver shaft coupling end configured for coupling to the driver shaft by a C-clip;

FIG. 34E is a side view of a driver shaft configured for coupling to a driver shaft-coupling end of the adapter illustrated in FIG. 34D according to some embodiments;

FIG. 35A is an isometric view of some embodiments of an implant kit comprising an adapter that is configured for coupling to an hammer toe implant using a collet;

FIG. 35B is an isometric view of some embodiments of an implant kit comprising an adapter that is configured for coupling to an hammer toe implant using a collet and showing a hammer toe implant received in the adapter;

FIG. 35C is an isometric view of some embodiments of an implant kit comprising an adapter that is configured for coupling to an hammer toe implant using a collet;

FIG. 35D is an end view of the implant kit illustrated in FIG. 35B;

FIG. 35E is cross-sectional view of the implant kit taken along line 25-25 in FIG. 35D;

FIG. 35F is cross-sectional view of the implant kit taken along line 25-25 in FIG. 35D;

FIG. 36A is an isometric view of another example of hammer toe implant according to some embodiments;

FIG. 36B is a top side view of the hammer toe implant illustrated in FIG. 36A;

FIG. 37 is a flow diagram of one example of method of installing an implant in accordance with some embodiments;

FIG. 38 illustrates a joint being accessed using a cutting tool in accordance with some embodiments;

FIG. 39 illustrates the middle and proximal phalangees of a foot being resected in accordance with some embodiments;

5

FIG. 40 illustrates a surgical device being inserted through the middle and distal phalanges in accordance with some embodiments;

FIG. 41 illustrates a second surgical device being inserted to a proximal phalange while the first surgical device remains disposed within the middle and distal phalanges in accordance with some embodiments;

FIG. 42A illustrates an implant and surgical device being disposed within the proximal phalange while the first surgical device remains disposed within the middle and distal phalanges in accordance with some embodiments;

FIG. 42B illustrates the implant being disposed within the proximal phalange after the second surgical device has been removed and while the first surgical device remains disposed within the middle and distal phalanges in accordance with some embodiments;

FIG. 43 illustrates the middle phalange having been pressed into engagement with the implant using the first surgical device as a guide in accordance with some embodiments;

FIG. 44 illustrates the first surgical device being advanced into the proximal phalange and metatarsal in accordance with some embodiments;

FIG. 45 illustrates one example of an end of the first surgical device having a blunted end while disposed within the middle, proximal, and distal phalanges and within the implant in accordance with some embodiments; and

FIG. 46 illustrates a hammer toe implant installed in the middle and proximal phalanges in accordance with some embodiments.

#### DETAILED DESCRIPTION

This description of preferred embodiments is intended to be read in connection with the accompanying drawings, which are to be considered part of the entire written description. The drawing figures are not necessarily to scale and certain features of the invention can be shown exaggerated in scale or in somewhat schematic form in the interest of clarity and conciseness. In the description, relative terms such as "horizontal," "vertical," "up," "down," "top," and "bottom" as well as derivatives thereof (e.g., "horizontally," "downwardly," "upwardly," etc.) should be construed to refer to the orientation as then described or as shown in the drawing figure under discussion. These relative terms are for convenience of description and normally are not intended to require a particular orientation. Terms including "inwardly" versus "outwardly," "longitudinal" versus "lateral," and the like are to be interpreted relative to one another or relative to an axis of elongation, or an axis or center of rotation, as appropriate. Terms concerning attachments, coupling, and the like, such as "connected" and "interconnected," refer to a relationship wherein structures are secured or attached to one another either directly or indirectly through intervening structures, as well as both movable or rigid attachments or relationships, unless expressly described otherwise. The term "operatively connected" is such an attachment, coupling or connection that allows the pertinent structures to operate as intended by virtue of that relationship.

FIG. 1 illustrates one example of an improved implant 100 for treating hammer toe. As shown in FIG. 1, implant 100 includes a threaded portion 102 and a blade portion 104, which are connected together at an engagement portion 106. In some embodiments, implant 100 has a substantially linear geometry. In some embodiments, implant 100 has an overall length of approximately 19 mm (approximately 0.75 inches) (e.g. 18.9-19.1 mm (0.74-0.76 inches)). In some embodi-

6

ments, blade portion 104 can be disposed at angle with respect to a longitudinal axis defined by the threaded portion 102. The angle can be between zero and 45 degrees, and more particularly between approximately five and fifteen degrees, although one skilled in the art will understand that implant 100 can have other dimensions and be provided in different sizes. For example, implant 100 can be provided in lengths of 16 mm and 22 mm, to name a few potential lengths.

In some embodiments, threaded portion 102 includes a plurality of threads 108 disposed along its entire length, which can be approximately 13 mm (approximately 0.5 inches) (e.g. 12.9-13.1 mm (0.49-0.51 inches)) although one skilled in the art will understand that threaded portion 102 can have other dimensions and be provided in different sizes. For example, threaded portion 102 can be provided in lengths of 10 mm and 15 mm, to name a few potential lengths. The tip 110 of threaded portion 102 can be pointed to facilitate the advancement of threads 108 into bone. Threads 108 can have a maximum outer diameter of approximately 2 mm (approximately 0.08 inches), although one skilled in the art will understand that thread portion 102 can have other dimensions and be configured to be received within a phalange bone of a person. For example, threads can have an outer diameter of approximately 2.4 mm and 1.6 mm, to name a few potential possibilities.

As shown in FIGS. 1-4 and 6, blade portion 104 can have a substantially cylindrical cross-sectional geometry. One skilled in the art will understand that blade portion 104 can have other cross-sectional geometries. In some embodiments, blade portion 104 can have a taper defined by a plurality of blades 112. For example, as best shown in FIGS. 2 and 3, the taper of blade portion 104 can be at an angle relative to the longitudinal axis defined by the elongated central portion of implant 100. In some embodiments, the taper is at an angle ( $\theta_T$ ) between 1 and 10 degrees relative to the longitudinal axis defined by the elongated central portion of implant 100. For example, the taper can be at an angle ( $\theta_T$ ) of approximately 5 degrees (e.g. 4.9-5.1 degrees) relative to the longitudinal axis defined by the elongated central portion of implant 100. In some embodiments, blade portion 104 includes a taper along its diameter defined by the plurality of blades 112. In the illustrated embodiments of FIGS. 2, 3 and 5, the plurality of blades 112 include a first blade 112 having a first diameter disposed proximate the engagement portion 106 and a second blade 112 having a second diameter smaller than the first diameter disposed proximate a terminating end 118 of the blade portion 104. In some embodiments, the first diameter can be approximately 5 mm (approximately 0.20 inches) (e.g. 4.9-5.1 mm) (0.19-0.21 inches) and the second diameter can be approximately 4.5 mm (approximately 0.18 inches) (e.g. 4.4-4.6 mm) although one skilled in the art will understand that the plurality of blades 112 can have other diameters and other dimensions. For example, the first diameter can be provided as in lengths of 4 mm and 6 mm, to name a few potential diameters. The inventors have found that the tapered blade portion 104 permits each successive blade 112 of blade portion 104 to achieve interference with bone during insertion which enhances fixation of the blade portion 104 compared to a non-tapered blade portion 104. In the illustrated embodiment, the blades 112 of blade portion 104 include a valley 126 between blades 112 and the teeth portions 114 of each blade 112. In some embodiments, valley 126 of teeth portions 114 of each blade 112 is substantially the same. In other embodiments, the valleys



126 of teeth portions 114 vary as the respective diameters of the successive blades are tapered.

In some embodiments, the terminating end 118 of blade portion 104 is a point, although one skilled in the art will understand that blade portion 104 can have a terminating end of other dimensions, sizes and/or shapes. In the illustrated embodiment of FIGS. 3 and 6, the terminating end 118 of blade portion 104 is cannulated. In various embodiments (FIGS. 3 and 6), the blade portion 104 and threaded portion 102 of implant 100 are cannulated. In some embodiments, implant 100 (FIGS. 3, 6, 11B) includes a groove 109 sized and configured to receive a k-wire, pin, or other surgical device or instrument that extends along the length of implant 100 in a direction that is parallel to a longitudinal length defined by implant 100. In some embodiments, the taper of blade portion 104 can be defined by the plurality of blades 112 having successively smaller diameters between a blade 112 disposed proximate engagement portion 106 and a blade 112 disposed proximate terminating end 118 of the blade portion 104.

In various embodiments, each blade 112 of the plurality of blades 112 of blade portion 104 include a plurality of grooved portions 116 and a plurality of teeth portions 114 to form a substantially cruciform cross-sectional geometry (FIG. 5). In the illustrated embodiment of FIG. 5, each blade 112 of blade portion 104 having a substantially cylindrical cross-section includes a plurality of substantially rounded grooved portions 116 formed along an axis parallel to a longitudinal axis of blade portion 104 and a plurality of teeth portions 114. As shown in FIGS. 1-5 and 6, blade portion 104 can have a substantially cylindrical cross-sectional geometry including a plurality of blades 112 having respective substantially cruciform cross-sectional geometries defined by a grooved portion 116 being disposed in each quadrant (112a-d) of each blade 112. In some embodiments, each blade 112 of blade portion 104 includes a pair of opposing grooved portions 116 (e.g. in quadrants 112b and 112d and in quadrants 112a and 112c respectively) to form a substantially cruciform cross-sectional geometry. As shown in FIG. 5, the grooved portions 116 of each pair of opposing grooved portions 116 (e.g. in quadrants 112a and 112c and 112b and 112d respectively) are substantially symmetrical. In the illustrated embodiment of FIG. 5, the grooved portions 116 disposed in each quadrant (112a-d) of each blade 112 are substantially symmetrical and the teeth portions 114 of each blade 112 are substantially symmetrical.

As shown more clearly in the illustrated embodiments of FIGS. 1, 3, 5 and 6, each blade 112 of blade portion 104 includes no flat surfaces. In some embodiments, a centerline of grooved portion 116 of each blade 112 of blade portion 104 is dimensioned such that it is tangent to respective diameters measured at the intersections of grooved portion 116 and the respective teeth portions 114. In the illustrated embodiments, grooved portions 116 are concave in shape and teeth portions 114 are convex in shape. In the illustrated embodiments, the respective surfaces of each blade 112 are rounded. In some embodiments, teeth portions 114 are serrated.

In some embodiments, engagement portion 106 can include a pair of protrusions extending from opposite sides of implant 100 and having rounded outer edges. In some embodiments, for example as shown in FIG. 2, the sides of the protrusions of engagement portion 106 can be substantially parallel with each other. In some embodiments, at least a portion of the implant 100 is cannulated (FIGS. 3, 6). The inventors have found that a cannulated implant 100 design

can permit surgeons to stabilize joints (e.g. a metatarsal phalangeal joint (MPJ)) during a surgical procedure.

Implant 100 is configured to be installed using a driving adapter 200 such as the one illustrated in FIGS. 7-10. The driving adapter 200 has an elongated body 202 having a proximal end 204 and a distal end 206. Body 202 of driving adapter 200 can have a circular cross-sectional geometry, although one skilled in the art will understand that body 202 can have other cross-sectional geometries including, but not limited to, triangular, rectangular, pentagonal, and hexagonal to name a few.

Proximal end 204 can be substantially solid and have a rounded tip 208. In some embodiments, proximal end 204 and distal end 206 can be cannulated such as, for example, to receive a k-wire. Distal end 206 can define a slot 210 sized and configured to receive blade portion 104 of implant 100 therein. In some embodiments, slot 210 can have a cylindrical cross-sectional geometry and have a depth that is sufficient to receive the entire blade portion 104 of implant 100 such that distal edges 212 of slot 210 contact the protrusions of engagement portion 106. In some embodiments, slot 210 can have a cylindrical, cruciform cross-sectional geometry and have a depth that is sufficient to receive the entire blade portion 104 of implant 100 such that distal edges 212 of slot 210 contact the protrusions of engagement portion 106. However, one skilled in the art will understand that slot 210 can have other cross-sectional geometries and dimensions. Slot 210 can extend through side walls 214 of body 202 as shown in FIGS. 7 and 8, or side walls 214 can completely enclose slot 210 as shown in FIGS. 9 and 10.

If the driving adapter 200 is to be used with an implant 100 having a substantially linear lengthwise geometry such as the implant 100 illustrated in FIGS. 1-6, then slot 210 can extend in a direction that is substantially parallel to an axis defined by body 202 of driving adapter 200. If driving adapter 200 is to be used with an implant 100 having a blade portion 104 that extends at an angle with respect to an axis defined by elongated threaded portion 102, then slot 210 can extend from distal edges 212 at an angle with respect to an axis defined by the length of body 202 such that elongated threaded portion 102 of implant 100 is linearly aligned with body 202 of driving adapter 200 as shown in FIGS. 11A and 11B. For example, if blade portion 104 of implant 100 extends at a ten degree angle with respect to an axis defined by elongated threaded portion 102, then slot 210 of driving adapter 200 can extend at a ten degree angle with respect to a longitudinal axis defined by body 202 such that threaded portion 102 of implant 100 and body 202 of driving adapter 200 are substantially linearly aligned.

A method of installing implant 100 in the proximal interphalangeal joint (PIP) 300 is described with reference to FIGS. 12A-16. However, one skilled in the art will understand that the technique for installing the implant 100 can be applied to other joints such as, for example, the distal interphalangeal (DIP) joint between middle phalange 304 and distal phalange 306. As shown in FIGS. 12A and 12B, an incision is made to open the PIP joint 300 and a cutting tool 400 having a blade 402 can be used to resect adjacent faces of proximal phalange 302 and middle phalange 304. The resected surfaces of proximal phalange 302 and middle phalange 304 can be debrided as understood by one skilled in the art.

Blade portion 104 of implant 100 can be disposed within slot 210 of driving adapter 200 as shown in FIGS. 11A and 11B. In some embodiments, the body 202 of driving adapter 200 can be cannulated. In some embodiments, a k-wire, pin

or other suitable surgical device can be inserted into the middle phalange 304 and driven through distal phalange and out of the end of the toe (not shown). A k-wire can be inserted such that a trailing end is disposed within middle phalange 304 or otherwise positioned with respect to the joint such that cannulated implant 100 can be driven into proximal phalange 302. In various embodiments, the body 202 of driving adapter 200 can be secured in a chuck 412 of a drill 410 or other driving instrument as shown in FIG. 13. Drill 410 or other driving instrument is used to drive the threaded portion 102 of implant 100 into the resected surface of proximal phalange 302. With the threaded portion 102 of implant 100 disposed within proximal phalange 302, driving adapter 200 can be disengaged from blade portion 104 of implant 100.

Middle phalange 304 can be predrilled or broached using drill 410 to create a hole 308 as shown in FIGS. 14 and 15. The predrilled or broached middle phalange 304 is then repositioned such that the predrilled hole or broach 308 aligns with the blade portion 104 of implant 100. In some embodiments, a dimension (e.g. diameter or width) of the predrilled hole or broach 308 is less than a dimension of blade portion 104 to permit a first blade 112 to achieve interference with the bone and enhance fixation of blade 104. For example, in some embodiments, "valley-to-valley" dimension of blade portion 104 (e.g. the diametrical dimension of blade portion 104 between blades 112). In some embodiments, a k-wire or other suitable surgical device is disposed within middle phalange 304 can be aligned with groove 109 of cannulated implant 100 (FIGS. 3, 6, 11B) disposed within proximal phalange 302. In various embodiments, the middle phalange 304 can be then pressed into engagement with the blade portion 104 as shown in FIG. 16. Serrated teeth portions or edges 114 of blade portion 104 help to maintain the engagement between middle phalange 304 and blade portion 104 of implant 100. In various embodiments, a k-wire or other suitable surgical device can be advanced into the joint, into and through middle phalange 302, into the respective metatarsal and through cannulated implant 100. In various embodiments, the k-wire or other suitable surgical device can remain within the patient for a period of time, e.g. minutes, hours, days or months, and can then be removed to leave behind cannulated implant 100.

FIGS. 17-27 illustrate some embodiments of a driver assembly 500 for installing an implant into bone. As shown in FIGS. 17 and 18, driver assembly 500 includes an adapter 502 coupled to a driving rod 516 onto which a handle 534 is over-molded or otherwise coupled. Adapter 502 includes a body 504 with a substantially rectangular side profile comprising side walls 506-1, 506-2, 506-3, and 506-4 (collectively referred to as "side walls 506") and a pair of end walls 508-1, 508-2 (collectively referred to as "end walls 508") having a substantially square geometry as best seen in FIGS. 19-22.

Body 504 defines a recess 510 along the length of side walls 506. Recess 510 is dimensioned such that an o-ring 544 (FIGS. 17 and 18) can be received therein. Additionally, recess 510 is located along side walls 506 at a distance from end walls 508 such that recess 510 is aligned with a valley 126 of teeth portions 114 along the circumference of blade portion 104.

End wall 508-1 defines an aperture 512 (FIG. 20) having a geometry that complements the cross-sectional geometry of blade portion 104 of implant 100. For example, if implant 100 has a cylindrical, cruciform straight blade portion 104 as illustrated in FIG. 2, then aperture 512 can extend approximately parallel to the lengthwise direction of side walls 506

(FIGS. 21-22). If the blade portion 104 of implant 100 is angled (not shown), then aperture 512 can extend from wall 508-1 at an angle relative to the plane defined by side wall 506-2 or 506-4 as will be understood by one skilled in the art. In some embodiments, aperture 512 has a depth that is greater than or equal to a length of blade portion 104 such that blade portion 104 can be received within body 504 and engagement portion 106 abuts end wall 508-1. Similarly, end wall 508-2 defines an aperture that is sized and configured to receive an end of elongated driving rod 516 therein.

As best seen in FIGS. 23-25, driving rod 516 includes a fin 518 disposed at a first end 520. Fin 518 disposed at end 520 of driving rod 516 has a rectangular shape and is sized and configured to be received within aperture 512 of adapter 502. Fin 518 defines a slot 522, which is sized and configured to receive a pin (not shown) for cross-pinning driving rod 516 to adapter 502. In some embodiments, end 520 can have other cross-sectional geometries including, but not limited to, triangular, square, and pentagonal, to name a few possibilities, that are configured to be received within aperture 514. Adapter 502 can be over-molded onto the end of driving rod 516. However, one skilled in the art will understand that adapter 502 can be cross-pinned or otherwise coupled to driving rod 516.

The opposite end 524 of driving rod 516 defines a pair of flats 526, 528, which are disposed on opposite sides of driving rod 516. As best seen in FIG. 23, flat 526 extends from tip 530 and is linearly spaced from flat 528, which is disposed at a greater distance from tip 530 than flat 526. However, one skilled in the art will understand that flats 526, 528 can be disposed at other positions along driving rod 516. Flats 526, 528 are configured to provide a contact surface for coupling to handle 532 (FIG. 26), which can be over-molded onto driving rod 516, such that rotation of handle 532 is translated to driving rod 516.

Turning now to FIGS. 26 and 27, handle 532 has an elongated body 534 that includes a plurality of ribs 536 that extend in a longitudinal direction along body 534 to provide a gripping surface for a user. As best seen in FIGS. 17 and 22, a smooth surface 538 interrupts circumferential ridges 540, which are disposed adjacent to proximal end 542 also for providing a gripping surface for a user.

Driver assembly 500 can be provided in a kit with a first adapter 502 for use with a straight implant 100 and a second adapter for use with an angled implant 100. A plurality of implants 100 of different sizes can also be provided in the kit. The kit can be used in an operation similar to the operation described above with respect to FIGS. 12A-16.

Blade portion 104 of implant 100 is disposed within aperture 512 of adapter 502 as shown in FIGS. 28A and 28B. With blade portion 104 disposed within aperture 512, an o-ring 544 (FIGS. 17 and 18) is placed in recess 510 defined by adapter 502 and within a valley 126 of serrated edges 112 along the top and bottom sides 114, 116 of blade portion 104. O-ring 544 secures implant 100 to adapter 502 such that implant does not move axially out of aperture 512.

Once implant 100 is secured to adapter 502, the surgeon uses handle 534 to manually drive threaded portion 102 of implant 100 into the resected surface of proximal phalange 302 as illustrated in FIG. 29. Implant 100 is driven into proximal phalange 302 until engagement portion 106 abuts proximal phalange 302. Implant 100 is decoupled from adapter 502 by axially pulling handle 534 away from implant 100 with sufficient force to flex o-ring 544 and separate adapter 502 from implant 100.

Middle phalange 304 can be predrilled or broached using drill 410 to create a hole 308 as shown in FIGS. 14 and 15.

11

The predrilled or broached middle phalange **304** is then repositioned such that the predrilled hole or broach **308** aligns with the blade portion **104** of implant **100**. The middle phalange **304** is then pressed into engagement with the blade portion **104** as shown in FIG. 16. Serrated teeth portions **114** of blade portion **104** help to maintain the engagement between middle phalange **304** and blade portion **104** of implant **100**.

The implant described above can advantageously be installed through a small incision as described above. Additionally, the improved implant is completely disposed within a toe of a patient, which prevents the implant from being caught on bed sheets or other objects like the conventional pins.

According to an aspect of the present disclosure, the implant can be preloaded into an adapter and provided as an implant kit. Various embodiments of such an implant kit will be described below.

FIG. 30 is a view of the implant kit **1000** in which the implant **100**, **100A** is preloaded into the adapter **502**. FIG. 30 is viewed from within the plane of FIGS. 28A and 28B so that the view shows the full circumference of the blade portion **104**, **104A**. In this view of FIG. 30, with the blade portion **104**, **104A** fully inserted into the adapter **502**, **502A**, an elastic O-ring **544** (also shown in FIGS. 17 and 18) placed in the groove **510** retains the implant **100**, **100A** in the adapter **502**, **502A** by preventing the implant from sliding out of the adapter. The cross-sections of the O-ring is shown in FIG. 30. The groove **510** is cut into the adapter with a sufficient depth so that when the O-ring **544** is placed therein the O-ring is positioned within the valley **126** between two adjacent teeth portions **114** about the circumference of the blade portion **104**, **104A**, as shown in FIG. 30. Because the O-ring **544** is elastic, one can push the blade portion **104**, **104A** of the implant into the adapter with sufficient force for one or more of the teeth portions **114** to push past the O-ring **544** when assembling the implant kit **1000**. Once the implant kit **1000** is assembled, however, the O-ring **544** secures and retains the implant **100**, **100A** in the adapter **502** until one intentionally pulls off the adapter **502** after the implant is driven into a bone.

In use, the surgeon would attach the implant kit **1000** to the driver tool **500** to manually drive the threaded portion **102** of the implant **100**, **100A** into the resected surface of proximal phalange **302** as illustrated in FIG. 29. The implant **100**, **100A** is driven into the proximal phalange **302** until engagement portion **106** abuts the proximal phalange **302**. The implant **100**, **100A** is then decoupled from the adapter **502** by axially pulling the adapter **502** away from the implant **100**, **100A** with sufficient force to push the O-ring **544** outward and separate the adapter **502** from the implant **100**, **100A**. Referring to FIGS. 31A through 35F, various embodiments for removably coupling the implant kits disclosed above to a driver shaft **516** of a driver tool **500** will be described. FIGS. 31A-31D are various views of some embodiments of an adapter such as the adapter **502** of FIGS. 28A, 28B, and 30 having a driver shaft coupling end configured for coupling to the adapter-engaging end **517a**, **517b** of the driver shaft. The driver shaft coupling end of the adapter **502** is provided with the longitudinally extending bore **514**, configured for receiving the adapter-engaging end **517a**, **517b**, and a pair of opposing tabs **541**, **542** extending longitudinally in the direction away from the implant engaging end. FIG. 31A shows a driver shaft **516** whose adapter-engaging end **517a** is configured with screw threads. In this embodiment, the driver-engaging end of the adapter **502** is configured to threadably couple to the adapter-engaging end

12

**517a** of the driver shaft **502** and the tabs **541**, **542** provide additional locking mechanism. FIG. 31B shows a driver shaft **516** whose adapter-engaging end **517b** is configured with a magnetic tip. In this embodiment, the driver-engaging end of the adapter **502** is configured to magnetically couple to the adapter-engaging end **517b** and the tabs **541**, **542** provide additional locking mechanism. The adapter **502** would then be provided with a magnet or a piece of magnetic material **503** for magnetically coupling to the adapter-engaging end **517b**.

FIGS. 31C and 31D are cross-sectional views of the adapter **502** showing the driver-engaging end. FIG. 31C shows the profile of the tabs **541** and **542** and the bore **514** for receiving the adapter-engaging end **517** of the driver shaft. If the adapter **502** is intended for use with the driver shaft **516** of the embodiment shown in FIG. 31A, the bore **514** is tapped with screw thread for threadably engaging the threaded adapter-engaging end **517a**. If the adapter **502** is intended for use with the driver shaft **516** of the embodiment shown in FIG. 31B, the bore **514** is provided with a magnet **530** for engaging the magnetized tip of the adapter-engaging end **517b**.

The tabs **541**, **542** and the adapter-engaging end **517a**, **517b** are configured for further mechanical coupling. In the illustrated example, the tabs **541**, **542** are provided with bumps **550** and the adapter-engaging end **517a**, **517b** of the driver shaft is provided with corresponding cutouts **560** for mating with the bumps **550**.

Shown in FIGS. 32A-32C are various views of an implant kit **1040** comprising an adapter **1502** and an implant **100** according to some embodiments. The implant **100** is removably coupled to the adapter **1502** at the adapter's implant-receiving end **1503** by a first O-ring **544** in the same manner as with the adapter **502** shown in FIGS. 19, 28A, 28B and 30. The adapter **1502** has a circumferential groove **1510**, in which the first O-ring **544** is provided, in the outer surface of the adapter in proximity to the implant-receiving end **1503**. As with the adapter embodiment **502**, the adapter **1502** comprises a slot provided in the implant-receiving end **1503** that receives the blade portion **104** of the implant **100**. The adapter **1502** also has a driver shaft coupling end **1504** configured for removably coupling to the driver shaft **516** by a second O-ring **546**. The driver shaft coupling end **1504** is provided with a longitudinally extending bore **1514** for receiving the adapter-engaging end **1517** of the driver shaft **516**. The driver shaft coupling end **1504** is also provided with a second circumferential groove **1512** in which the second O-ring **546** is disposed. The adapter-engaging end **1517** has a cross-section that is larger than the inner diameter of the second O-ring **546** but has a turned down section **1518** that has a reduced cross-section for accommodating the second O-ring **546** when the adapter-engaging end **1517** is inserted into the bore **1514** as shown in FIG. 32C. When the adapter-engaging end **1517** is inserted into the bore **1514**, the turned down section **1518** and the second circumferential groove **1512** align so that the second O-ring **546** rests in the turned down section **1518**. The second O-ring **546** thus provides an interference with the adapter-engaging end **1517** to prevent the adapter **1502** and the driver shaft **516** from decoupling without exerting some force.

FIGS. 33A-33C are various views of an adapter **2502** that can be used in an implant kit **1050** according to some embodiments of the present disclosure. The adapter **2502** has an implant receiving end **2503** configured to couple to an implant **100** by an O-ring **544** according to the adapter of FIGS. 19, 28A and 28B and a driver shaft coupling end **2504** configured for coupling to the driver shaft **516** by an off-set

13

clip **2515**. The driver shaft coupling end **2504** has a longitudinally extending bore **2514** for receiving an adapter-engaging end **2517** of the driver shaft **516**. The off-set clip **2515** is cantilevered to the adapter having a cantilever portion **2515a** connected to the adapter body and a locking portion **2515b** extending orthogonal to the cantilever portion **2515a**. The locking portion **2515b** is provided with a through hole **2516** for the adapter-engaging end **2517** of the driver shaft **516**. The through hole **2516** and the bore **2514** are off-set to enable the locking function. The adapter-engaging end **2517** is provided with a groove or a cutout **2518** on one side for removably engaging the off-set clip **2515**. To insert the adapter-engaging end **2517** into the adapter, the user pushes the off-set clip **2515** in the direction shown by the arrow P in FIG. 33C, which is a longitudinal cross-sectional view of the adapter **2502**. That will deflect the cantilever portion **2515a** in the direction P and bring the through hole **2516** in linear alignment with the bore **2514** so that the adapter-engaging end **2517** can be inserted through the through hole **2516** and the bore **2514**. Once the adapter-engaging end **2517** is fully inserted, the off-set clip **2515** is released to its normal off-set position as shown in FIG. 40C. The off-set position of the locking portion **2515b** keeps the locking portion **2515b** seated within the cutout **2518** keeping the driver shaft **516** coupled to the adapter **2502**. The off-set clip can be configured so that in the configuration shown in FIG. 33C, the locking portion **2515b** maintains a force against the cutout **2518** in the direction opposite the arrow P. To remove the adapter **2502** from the adapter-engaging end **2517**, the off-set clip **2515** is pushed in the direction of the arrow P shown in FIG. 33C bringing the through hole **2516** and the bore **2514** into longitudinal alignment and thus removing the interference between the locking portion **2515b** and the cutout **2518**. In some embodiments, the adapter-engaging end **2517** may simply be straight without the cutout **2518** structure. In that embodiment, the urging of the locking portion **2515b** against the straight adapter-engaging end **2517** in the direction opposite the arrow P will provide sufficient frictional interference to keep the driver shaft **516** and the adapter **2502** coupled.

FIGS. 34A-34E are various views of the driver shaft coupling end **3504** of an adapter **3502** that is configured for removably coupling to the implant **100** to form an implant kit according to some embodiments. The implant-receiving end of the adapter **3502** is configured to couple to the implant by an O-ring **544** according to the adapter of FIGS. 19, 28A and 28B. The driver shaft coupling end **3504** is configured to removably couple to the adapter-engaging end **3517** of the driver shaft **516** by a C-clip **3550**. The C-clip **3550** is generally shaped like a letter C and has two prongs **3550a** and **3550b** joined at one end and open at the opposite end. The driver shaft coupling end **3504** of the adapter **3502** is provided with a bore **3514** for receiving the adapter-engaging end **3517**. The driver shaft coupling end **3504** is further configured with a pair of slots **3512** for receiving the C-clip **3550** and oriented orthogonal to the longitudinal axis of the adapter **3502**. FIG. 34B is an end view of the adapter assembly viewed from the driver shaft coupling end **3504** showing the C-clip **3550** clipped on to the adapter **3502** by sliding the two prongs **3550a**, **3550b** into the pair of slots **3512**. The pair of slots **3512** are cut into the adapter **3502** sufficiently deep to overlap with the bore **3514** so that when the C-clip **3550** is clipped on to the adapter **3502**, interference tabs **3551** on each of the two prongs **3550a**, **3550b** protrude into the bore **3514** as shown in FIG. 34B. When the adapter-engaging end **3517** of the driver shaft **516** is inserted into the bore **3514** and locked with the C-clip **3550** as shown

14

in the longitudinal cross-sectional view of FIG. 34E, the interference tabs **3551** reside in the corresponding slots **3518** provided in the adapter-engaging end **3517** and prevent the adapter **3502** and the driver shaft **516** from decoupling. In this embodiment, the interference tabs **3551** are oriented substantially parallel to one another. In one preferred embodiment, the interference tabs **3551** can be oriented in a slant so that the interference tabs **3551** are tapered towards the open end of the C-clip **3550**. The tapered interference tabs **3551** makes is easier to insert the C-clip **3550** over the adapter-engaging end **3517**.

FIGS. 35A-35F are various views of some embodiments of an implant kit **1030** comprising an adapter **2600** configured for coupling to a hammer toe implant **100** using a thread-biased collet **2650**. The adapter **2600** comprises a sleeve **2602** and the collet **2650**. The sleeve **2602** has openings at each end and a bore **2615** longitudinally extending between the two openings. As shown in FIGS. 35A and 35B, sleeve **2602** can include a plurality of ribs that extend in a longitudinal direction along sleeve **2602** to provide a gripping surface for a user. The collet **2650** is received in the bore **2615**. The sleeve **2602** has a first end **2605** that forms one of the openings.

Referring to FIG. 35A, the collet **2650** is generally cylindrical in shape and comprises an implant receiving portion **2657** and a threaded portion **2660**. The threaded portion **2660** is provided with screw threads **2663**. The implant receiving portion **2657** has an implant-receiving opening **2612** for receiving the blade portion **104** of the implant **100**. The implant-receiving opening **2612** is defined by collet segments **2651** which are defined by slots **2652** extending from the implant-receiving end towards the threaded portion **2660**. This example of a collet has two collet segments **2651**. The implant receiving portion **2657** is flared in its outer circumference so that the diameter of the receiving portion **2657** increases towards the implant-receiving end of the collet. FIG. 35B shows the collet **2650** with the implant **100** received in the slots **2652**. FIG. 35C shows the collet with an indicated direction of rotation L to drive the sleeve **2602** onto the threaded portion **2660** to retain the implant **100** within implant receiving portion **2657**. In various embodiments, the refraction and extension of the collet **2650** is enabled by turning the sleeve **2602** about a longitudinal axis relative to the collet **2650** thus engaging the screw threads **2607** and **2663**. In some embodiments, sleeve **2602** is driven by hand in direction of rotation L to retain implant **100** within implant receiving portion **2657** pre-implantation and in an opposite direction of L to release implant **100** post-implantation.

FIG. 35D is an end view of the adapter **2600** illustrated in FIGS. 35A-35C and shows the implant **100** received in the implant receiving end **2657** and slots **2652**. The implant-receiving opening **2612** of implant receiving portion **2657** has a geometry that complements the cross-sectional geometry of blade portion **104** of implant **100** and is defined by collet segments **2651** which are defined by slots **2652**. For example, if implant **100** has a cylindrical, cruciform straight blade portion **104** as illustrated in FIG. 2 and FIG. 35A, then implant-receiving opening **2612** can extend approximately parallel to the lengthwise direction of collet **2650**. If the blade portion **104** of implant **100** is angled (not shown), then implant-receiving opening **2612** can extend from end **2603** at an angle relative to the plane defined by collet **2650** as will be understood by one skilled in the art. In various embodiments, as shown in FIGS. 35A and 35D, collet segments

15

2651 of implant receiving end 2657 include radii features to complement radii features of the cylindrical, cruciform blade portion 104.

Referring now to FIGS. 35E and 35F, the bore 2615 has a screw threaded portion 2607 and a main portion 2605. The threaded portion 2607 is configured to threadably engage the threads 2663 of the collet 2650. The main portion 2605 has a sufficiently large diameter to accommodate a substantial portion of the implant receiving portion 2657 of the collet 2650 without imposing any mechanical interference. The main portion 2605 terminates at the first end 2603 where the opening formed therein has a diameter smaller than the maximum diameter of the flared implant receiving portion 2657. This configuration allows the collet segments 2651 to be constricted by the first end 2603 when the collet 2650 is retracted into the sleeve 2602 in the direction R shown in FIG. 35F and close in on the blade portion 104 of the implant 100, thus, retaining the implant. Conversely, the implant 100 can be released from the adapter 2600 by extending the collet 2650 outward from the sleeve 2602 in the direction E shown in FIG. 35F. In some embodiments, and as shown in FIG. 35F, sleeve 2602 includes an internal taper to interface with an external taper of the implant receiving portion 2657 of collet 2650.

FIGS. 36A and 36B illustrate one example of an implant 100A that can be used with the two-wire insertion technique described herein. Implant 100A is identified to implant 100 except that implant 100A includes a central passageway 101 that extends through the entire length of implant 100A. Descriptions of the features of implant 100A that are identical to the features of implant 100 are not repeated.

FIG. 37 is a flow diagram of one example of installing a hammer toe implant using a two-wire technique in accordance with some embodiments. Method 2000 depicted in FIG. 37 is described with reference to FIGS. 38-45, which illustrate various steps of installing a hammer toe implant. Although the following descriptions are provided with respect to installing implant 100A, it will be appreciated that implants having other shapes and configurations can be used so long as they include a passageway for accommodating a k-wire as will be apparent after reading the following description. One example of such an alternative implant is disclosed in commonly assigned U.S. patent application Ser. No. 14/043,105, filed Oct. 1, 2013 and entitled "Hammer Toe Implant and Method," the entirety of which is incorporated by reference herein. As will be appreciated by one of ordinary skill in the art, the implants can have other fixation features. For example, both ends of the implant can have blades instead of one blade portion and one threaded portion. In some embodiments, the implant can include a blade or threaded portion at one end and an expanding portion (e.g., divergent legs or arms) at the opposite end.

Further, although method 2000 is described as installing an implant in the bones of a proximal interphalangeal joint (PIP) 300, i.e., the joint between proximal phalange 302 and middle phalange 304, one of ordinary skill in the art will understand that the technique may be applied to other joints, such as, for example, the distal interphalangeal (DIP) joint, i.e., joint 308 between middle phalange 304 and distal phalange 306.

At block 2002 of FIG. 37, an incision is made to expose the PIP joint 300. For example, FIG. 38 illustrates one example of the PIP joint 300 being exposed by using a cutting tool 400 having a blade 402.

At optional block 2004 (FIG. 37), the blade 402 of a cutting tool 400, such as a saw, is used to resect one or both of the adjacent faces of proximal phalange 302 and middle

16

phalange 304 as illustrated in FIG. 39. The resected surfaces of proximal phalange 302 and middle phalange 304 can be debried as understood by one skilled in the art.

At block 2006 (FIG. 37), bones are flexed apart and a first k-wire, pin, or other surgical device 10-1 is inserted into the proximal face of middle phalange 304. In some embodiments, the leading end 10A-1 of wire 10-1 is forced across the joint between middle phalange 304 and distal phalange 306, through distal phalange 306, and out the distal tip 306A of distal phalange 306 as shown in FIG. 40. The k-wire 10-1 continues to be advanced until the trailing end 10B-1 is disposed adjacent to the proximal face 304A of middle phalange 304 such that joint 300 is accessible. For example, the trailing end 10B-1 of wire 10-1 can extend slightly from or be flush with the proximal face 304A of middle phalange 304. In some embodiments, trailing end 10B-1 is disposed entirely within middle phalange 304.

At block 2008 (FIG. 37), a second k-wire or pin 10-2 is inserted into the exposed distal face 302A of proximal phalange 302 while the first wire 10-1 is still disposed within middle phalange 304 and distal phalange 306 as shown in FIG. 41. In some embodiments, leading end 10A-2 of wire 10-2 is advanced such that it is disposed within proximal phalange 302. However, in some embodiments, leading end 10A-2 is further advanced such that it is received within metatarsal 310 and/or cuneiform (not shown).

At block 2010 (FIG. 37), implant 100A is driven into engagement with proximal phalange 302 as shown in FIG. 42A. In some embodiments, the implant 100A is driven into proximal phalange 302 using wire 10-2 as a guide. For example, the implant 100A is slid over trailing end 10B-2 of wire 10-2 by receiving wire 10-2 within passageway 101 of implant 100A. An installation tool, such as one of driver assembly 500 and/or installation kit 1030, including adapter 2600, can be used to engage the blade portion 104 of implant 100A and drive threaded portion 102 into middle phalange 302 as implant 100A is guided by wire 10-2.

At block 2012 (FIG. 37), second k-wire or pin 10-2 is removed from its engagement with implant 100A and proximal phalange 302 (and metatarsal 310 and cuneiform (not shown), if applicable). Implant 100A remains engaged with proximal phalange 302 once wire 10-2 has been removed as shown in FIG. 42B.

At block 2014 (FIG. 37), the middle phalange 304 is moved into engagement with implant 100A. For example, with wire 10-1 still disposed within middle and distal phalanges 304, 306, the middle and distal phalanges 304, 306 and wire 10-1 are manipulated such that the trailing end 10B-1 of wire 10-1 is aligned with the passageway 101 of implant 100A. In some embodiments, wire 10-1 can be inserted into passageway 101 prior to the middle phalange 304 being forced into engagement with the blade portion 104 of implant 100A as shown in FIG. 43.

At optional block 2016 (FIG. 37), end 10B-1 of k-wire 10-1 is advanced through proximal phalange 302, and into metatarsal 310 (and/or cuneiform (not shown)) as shown in FIG. 44.

At optional block 2018 (FIG. 37), what was initially leading end 10A-1 (FIGS. 40, 41, 42A, and 42B), is blunted or capped to provide an exposed blunt end 10C-1 as shown in FIG. 45.

At block 2020, after the surgical device 10-1 remains within a patient for a period of time, e.g., minutes, hours, days, or months, the surgical device 10-1 is removed to leave behind implant 100A as shown in FIG. 46.

Although the invention has been described in terms of exemplary embodiments, it is not limited thereto. Rather, the

17

appended claims should be construed broadly, to include other variants and embodiments of the invention, which may be made by those skilled in the art without departing from the scope and range of equivalents of the invention.

Some embodiments provide an implant including an elongated threaded portion and a blade portion extending from the elongated threaded portion. The blade portion has a substantially cylindrical cross-sectional geometry and a taper defined by a plurality of blades.

Some embodiments provide an implant including an elongated threaded portion and a blade portion extending from the elongated threaded portion. The blade portion includes a plurality of blades having respective substantially cruciform cross-sectional geometries defined by a grooved portion being disposed in each quadrant of each blade.

Some embodiments provide a method including forming an incision to gain access to a joint between first and second bones, flexing the first and second bones such that the bones are disposed at an angle from one another, and advancing a threaded portion of an implant into the first bone. The implant includes a blade portion extending from an elongated threaded portion. The blade portion has a substantially cylindrical cross-sectional geometry and a taper defined by a plurality of blades. The method also includes repositioning the second bone such that a middle of the second bone is approximately aligned with the blade portion of the implant and forcing the second bone into engagement with the blade portion of the implant.

Although the invention has been described in terms of exemplary embodiments, it is not limited thereto. Rather, the appended claims should be construed broadly, to include other variants and embodiments of the invention, which can be made by those skilled in the art without departing from the scope and range of equivalents of the invention.

What is claimed is:

1. A method, comprising:

inserting a first surgical device into an exposed first end of a first bone until a trailing end of the first surgical device is disposed adjacent to the first end of the first bone;

inserting a second surgical device into an exposed first end of a second bone while the first surgical device remains disposed within the first bone;

advancing a first portion of an implant into the second bone while being engaged with a passageway defined by the implant such that the implant is guided by the second surgical device;

removing the second surgical device from the second bone and from its engagement with the implant;

repositioning the first bone such that the first surgical device is aligned with the passageway defined by the implant; and

forcing the first bone into engagement with a second portion of the implant.

2. The method of claim 1, further comprising

forming an incision to gain access to a joint between the first bone and the second bone;

flexing the first bone relative to the second bone to expose the first end of the first bone and the first end of the second bone; and

resecting at least one of the first end of the first bone and the first end of the second bone.

3. The method of claim 1, further comprising removing the first surgical device from the first bone and its engagement with the implant.

18

4. The method of claim 1, wherein the passageway is a central passageway that extends through the entirety of the implant.

5. The method of claim 1, wherein the first portion of the implant is a threaded portion and the second portion of the implant is a blade portion.

6. A method, comprising:

forming an incision to gain access to a joint between first and second bones;

flexing the first and second bones such that the first and second bones are disposed at an angle with respect to one another;

inserting a first surgical device into the first bone until a first end of the first surgical device is disposed adjacent to a first end of the first bone;

inserting a second surgical device into the second bone while the first surgical device remains disposed within the first bone;

advancing a first portion of an implant into the second bone while a passageway defined by the implant is engaged with the second surgical device such that the implant is guided by the second surgical device;

removing the second surgical device from the second bone and from its engagement with the implant;

repositioning the first bone such that the first surgical device is aligned with the passageway defined by the implant; and

forcing the first bone into engagement with a second portion of the implant.

7. The method of claim 6, further comprising removing the first surgical device from the first bone and its engagement with the implant.

8. The method of claim 6, further comprising resecting an end of each the first and second bones prior to inserting the first and second surgical devices.

9. The method of claim 6, wherein the first bone is a middle phalange of a foot, and the second bone is a proximal phalange of the foot.

10. The method of claim 9, wherein the first portion of the implant is a threaded portion and the second portion of the implant is a blade portion.

11. A surgical method, comprising:

gaining access to a joint between a middle phalange and a proximal phalange;

inserting a first end of a first surgical device into a proximal end of the middle phalange;

advancing the first surgical device into the middle phalange and a distal phalange until a second end of the first surgical device is disposed adjacent to the proximal end of the middle phalange;

inserting a first end of a second surgical device into a distal end of the proximal phalange while the first surgical device remains disposed within the middle and distal phalanges;

advancing a first portion of an implant into the proximal phalange using the second surgical device as a guide;

removing the second surgical device;

inserting the first surgical device into a passageway defined by the implant while the first surgical device remains disposed within the middle and distal phalange; and

removing the first surgical device from its engagement with the implant, middle phalange, and distal phalange.

12. The surgical method of claim 11, further comprising: advancing a second end of the first surgical device through the proximal phalange and into at least one of a metatarsal and a cuneiform; and

blunting the first end of the first surgical device.

19

13. The surgical method of claim 12, further comprising, after a period of time, removing the first surgical device while the implant remains engaged with the proximal phalange and the middle phalange.

14. The surgical method of claim 11, further comprising 5  
resecting an end of each the middle phalange and the proximal phalange prior to inserting the first and second surgical devices.

15. The surgical method of claim 11, wherein the passageway is a central passageway that extends through the 10  
entirety of the implant.

16. The surgical method of claim 11, wherein the first portion of the implant is a threaded portion and the second portion of the implant is a blade portion.

\* \* \* \* \*

15

20